Submitter :

Date: 09/13/2005

Organization :

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-361-Attach-1.DOC

JENNINGS BEHAVIORAL HEALTH, LLC

619 NORTH MAIN STREET
JENNINGS, LA 70546
337-824-4300 – PHONE
337-824-4315 – FAX
MARTINT@JBHLLC.COM

To: CMS
From: Tehjan Martin RN,C
Date: 9/13/05
Re: CMS – 1501-P 2006 Proposed Payment Rates

COMMENTS TO PROPOSED RULE

1. Concern over the drop in payment rate
   Jennings Behavioral Health LLC has two CMHC's. One in Jennings Louisiana and one in Sulphur Louisiana. The proposed cuts in the APC-033 will drastically reduce our ability to provide services to Medicare beneficiaries. The cuts will mean a net payment rate of $167.00 per day in our Sulphur program and $162.00 per day in our Jennings program. This is clearly not a sufficient rate to cover providing a structured program for the chronically mentally ill, consisting of at least 4 groups per day, five days per week, all of professional services.

   I question how it is possible that your data is correct when CMS has recognized that the 2006 payment rate for an outpatient group therapy session (HCPCS Code 90853) is $77.93. A partial day program is a minimum of 4 therapy sessions per day; therefore it would be logical to have a gross payment rate of $311.72(4*$77.93) for the total services rendered rather than the proposed rate of $240.51.

   Services provided in an outpatient department of a hospital, as mentioned above, are for less acute patients, requiring a lower level of service. It is only reasonable that PHP is reimbursed at a higher rate since the population is more acute.

2. Lack of protection for rural providers
   I am concerned that CMS again fails to protect rural mental health providers. There has been well documented evidence, published by CMS, of the special hardships and needs of rural providers. Most other rural provider types have been recognized for this hardship and have had allowances and special provisions to ensure their viability. CMHC's have long been asking for this protection and some assistance for rural providers. We ask that you consider treating CMHC's in an equitable manner to other provider types.

Tehjan Martin RN,C
CEO

Submitter : **Mr. Dan Eckels** **Date: 09/13/2005**

Organization : **Washington Regional Medical Center**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

To whom it may concern:

In the July 25, 2005, Federal Register notice, CMS proposed to pay for outpatient drugs and biologicals at 106 percent of average sales price (ASP).

Please show how this 6% was derived. Our cost of pharmacy personnel is 44% of drug costs plus other costs/systems to manage and distribute the drugs. Six percent is absolutely unrealistic.

Dan Eckels
Sr. VP and CFO
Washington Regional
479-463-2825
deckels@wregional.com

Submitter : **Dr. Martin Kelvas** **Date: 09/13/2005**

Organization : **St Thomas Hospital**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

This is with reference to the proposed Outpatient Prospective Payment System (OPPS) rates for 2006. The Centers for Medicare & Medicaid Services (CMS) planned change of reimbursement for drugs and biologicals in outpatient settings will have a major impact on our bottom line at St Thmomas Hospital.

The report dated June 30, 2005, on hospital outpatient department pharmacy handling costs prepared by the Medicare Payment Advisory Commission (MedPAC) noted that these expenses were 'not insignificant' and that they 'made up 26 percent to 28 percent of pharmacy departments' direct costs.' Instead of accepting MedPAC's analysis, CMS proposes to pay only an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs.

This reimbursement formula is inadequate to cover handling costs of
drugs. Hospitals may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

I support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

Thank you for your this opportunity to be voice my concerns.

Submitter : **Mr. Jim Willett** **Date: 09/13/2005**

Organization : **Mr. Jim Willett**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS:

I'm a practicing hospital pharmacist and I would like to offer my personal comments regarding CMS-1501-P,"Changes to Hospital Outpatient Prospective Payment System and Calendar year 2006 payment rates".

It is my understanding that CMS is proposing to include a 2% add-on adjustment to cover pharmacies' "handling costs" - labor and benefits, space, equipment, supplies, and support contracts -- that are associated with the storage, preparation, transport, and disposal of drugs and biologicals.

I believe these adjustment are far too inadequate to cover basic acquisition and handling costs associated with the complex medications frequently utilized in the outpatient setting.

A June 30, 2005, report on hospital outpatient department pharmacy handling costs prepared by the Medicare Payment Advisory Commission (MedPAC) noted that these expenses were "not insignificant" and that they "made up 26 percent to 28 percent of pharmacy departments' direct costs."

This reimbursement formula will be a hardship for all hospitals, especially smaller hospitals, that may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change, and to the detriment of patients who will not receive treatment by their providers of choice.

Inadequate reimbursement to hospital outpatient departments may have an adverse impact on quality, safety and level of their services.

I urge CMS to fully support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

Thank you for consideration of my comments.

Submitter :

Date: 09/13/2005

Organization :

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

I am an audiologist that works with hearing impaired patients on a daily basis. Many patients with hearing loss are older and Medicare is their primary insurance. They depend greatly on Medicare payment. Cochlear implants are one option for people that are profoundly impaired where hearing aids are no longer beneficial. The current proposal would reduce the payment for such a procedure. If the payment is lowered below the cost, many professionals will be forced to discontiue providing such services. My request is that this issue be carefully examined. This would severely impace Medicare beneficiaries access to such services. I request that you do not lower payment below 2005 and also consider inflation and other update factors. Your help and consideration on such issues is greatly appeciated.

Submitter : Althea Alderson **Date:** 09/13/2005

Organization : John C Lincoln Hospital

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

RE: CMS proposal to include a 2% add-on adjustment to cover pharmacies' "handling costs" - labor and benefits, space, equipment, supplies, and support contracts -- that are associated with the storage, preparation, transport, and disposal of drugs and biologicals.
Comment: Please reconsider the % being alloted for handling costs. with the USP 797 requirements and the increased cost of cytotoxic waste the proposed % may require us to discontinue offering Outpatient services at our hospital. To dispose of 1 x 18 gallon chemotherapy waste container alone, costs us $800.00. This size container will only accomodate waste for 4-5 procedures.
We are being penalized for meeting standards. Please look at the current practices and adopt costs more in line with today.
Thank you for listening.

Submitter : Dr. Roy Guharoy

Date: 09/13/2005

Organization : SUNY-Upstate Medical University

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I am requesting you to consider the report on hospital outpatient pharmacy handling costs prepared by the Medicare Payment Advisory Commission. The report noted that these expenses were "not insignificant" and that they "made up 26 percent to 28 percent of pharmacy departments' direct costs."
It does not make any sense that you are not accepting the report and proposing to pay only an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs. The reimbursement formula is inadequate to cover handling costs of drugs. Small hospitals, particularly, may be forced to limit or eliminate the treatment of patients in outpatient settings. Your proposal is going to adversely impact patient care. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. In addition, some patients will be forced to go to private clinics resulting in higher expense for the CMS. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.
I do strongly support the proposal being made by the Association of Community Cancer Centers (ACCC) which states that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital. You need to collect hospital charge data for overhead costs for two years to determine if even the 8% rate is adequate and consider new reimbursement rates for these costs for payment in 2008.

Thank you,

Roy Guharoy, Pharm.D.,FCP,FCCP,FASHP
Director of Pharmacy Services
SUNY-Upstate Medical University
Syracuse, NY

Submitter : Mr. Michael Rodgers **Date: 09/13/2005**

Organization : Catholic Health Association of the United States

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-368-Attach-1.DOC

September 9, 2005

Honorable Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1501-P

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Dr. McClellan:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the notice of proposed rulemaking (NPRM), Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (*Federal Register*, Vol. 70, No. 141, pages 42673-43011) published July 25, 2005.

1. Inpatient Procedures

CHA urges CMS to eliminate the inpatient procedure list primarily because the list is not binding on physicians.

The list was created to identify procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the Hospital outpatient prospective payment system (OPPS). There are numerous problems created by the inpatient procedure list as has been documented in past comments. The biggest continuing problem is that such a list is not binding on physicians. Since the physician only receives payment when a procedure on the inpatient list is performed on an outpatient basis, there is no incentive for the physician to be concerned whether Medicare will pay the hospital for the procedure. This fact underscores the fact that it is the physician, not the hospital, who determines whether a procedure will be performed in the outpatient or inpatient setting.

In the past, CMS has responded to such comments by saying that "[it] believes that appropriate education of physicians and other hospital staff by CMS, hospitals and organizations representing hospitals is the best way to minimize any existing confusion." From our perspective, having hospitals or their representative organizations try to educate physicians on the appropriate use of the inpatient procedure list tends to be fruitless. When it comes to economic issues, physicians, quite understandably, pay little attention

to how hospitals are paid. In addition, the CMS provider education staff appears to have made little headway on this matter as well.

This issue was initially raised when CMS first published the inpatient procedure list in 2000, and the situation has not improved. In fact, it has worsened, as physicians are now much more focused on increasing outpatient procedure volume.

2. APC Relative Weights

CHA continues to object to the year-to-year volatility of the APC weights and urges CMS to take appropriate steps to ensure stability in APC weights. One approach is to adjust medians derived from claims data to limit the amount of change that occurs from year-to-year. CHA recommends a stabilization policy which adjusts the medians from claims data to ensure that no APC medians fall more than 5 percent above or below medians used for payment in CY 2005.

The CY 2006 proposed rule shows significant swings in the APC weights. For 65 APCs, the 2006 proposed weights would decrease by 10 percent or more; for 11 of these, the reduction is greater than 20 percent. In total, weights would be lower for 235 APCs. On the other hand, weights increase for 176 APCs, going up 10 percent or more for 46 of them. In fact, 21 APCs would rise by 30 percent or more. This high level of unpredictability in APC weight changes is not acceptable and should be moderated by CMS.

3. Device-Dependent APCs

CHA strongly recommends that CMS, for CY 2006, continue the CY 2005 policy of limiting device dependent APC payment losses to no more than 5 percent of the median costs determined for the prior accounting year. Specifically, continuation of this policy would ensure hospitals are paid the higher of either the CY 2006 unadjusted median, or 95 percent of the adjusted median determined for CY 2005.

In CY 2005 CMS adopted the above policy to begin the transition to the use of pure claims data for all APC services in order to ensure the appropriate relativity of the median costs for all payable OPPS services. While CHA understands and appreciates this goal, we believe such a transition must be deliberate because too much is at stake for unnecessary haste. The policy must do a better job of balancing the desirability of the goal and the continued availability of critical and essential outpatient services for Medicare beneficiaries.

A cut of support from 95 percent to 85 percent of the CY 2005 median could well tip the scale against the continued offering of such services, a most undesirable effect. Our rationale is based on the fact that, since HCPCS codes were not required in 2004, CMS still does not have adequate data to be used in calculating the payment rates for device dependent APCs. Specifically, CMS has used claims data both with and without C-codes

to generate the APC payment rates for device dependent APCs. At a minimum, CHA urges CMS to only use correctly coded single procedure claims.

4. Outlier Payments

CHA urges CMS to provide a technically supportable rationale for reducing the projected target for aggregate outlier payment from 2.0 percent to 1.0 percent of aggregate total payments under the OPPS.

While CMS proposed to reduce the projected target for aggregate outlier payments from the original 2.0 percent to 1.0 percent, it did not provide any analytical support for this policy decision. Instead, CMS cited a number of reasons for its decision, but provided no supporting analytical rationale.

In the proposed rule, one reason cited by CMS for the proposed reduction was that "the distribution of outlier payments benefits some hospital groups more than others." This is true for the inpatient PPS as well, but in this case CMS has not proposed minimizing the outlier pool consistent with the statute. The above hardly seems sufficient reason to reduce the pool – as this observation could also be viewed as signaling a continuing protection need which benefits only certain types of facilities.

In closing, CHA appreciates opportunity to provide CMS with our comments on the proposed hospital outpatient PPS rule for CY 2006 and hopes our recommendations are helpful in developing the final rule.

Sincerely,

Michael Rodgers

Interim President and CEO

Submitter : **Mrs. Valerie Rinkle** **Date: 09/13/2005**

Organization : **Provider Roundtable % Asante Health System**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached Word Document for the Provider Roundtable Comments.

CMS-1501-P-369-Attach-1.DOC

Ardent Health Services, TN
Asante Health System, OR
Avera Health, SD
Baptist Healthcare System, KY
Carolinas Healthcare System, NC
Community Hospital Anderson, IN
Forrest General Hospital, MS
Health First, Inc., FL
Mercy Medical Center, IA
OhioHealth Corporation, OH
Our Lady of Lourdes Regional Medical Center, LA
Saint Joseph's Hospital, WI
Saint Mary's Hospital, MN
Sisters of Mercy Health System, MO
Southwestern Vermont Medical Center, VT
University of Colorado Hospital, CO
University Health System, TX
White River Medical Center, AR

September 16, 2005

Submitted electronically: http://www.cms.hhs.gov/regulations/ecomments
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS-1501-P

Dear CMS:

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers from around the country who gathered to provide comments on the 2006 Outpatient Prospective Payment (OPPS) Proposed Rule, as published in the *Federal Register* on July 25, 2005. The providers listed above appreciate the opportunity to submit these comments for consideration by CMS. A full list of the current PRT members is provided in **Appendix A**.

Introduction

The Provider Roundtable (PRT) is a group of providers representing 18 different hospitals and health systems from around the country. Like many others, our hospitals, and the departments within our institutions, continue to struggle with OPPS and its many coding and billing complexities. Providers are often too busy, or unaware of the overall process, to submit comments to CMS on their own. Therefore, the members of the PRT collaborated to provide substantive comments with an operational focus which CMS' staff should consider during the OPPS policymaking and recalibration process each year.

We appreciate the opportunity to provide CMS with our comments, and recognize that providers must become involved in the comment process if OPPS is to improve with time.

1. Relative Weights

Bypass list

If the PRT understands correctly, the expanded bypass list that CMS is using resulted in the creation and use of more single procedure claims for the purposes of setting APC relative weights. We are very supportive of this, but remain concerned about two E/M codes that appear on the bypass list. If our understanding is correct, a code is placed on the bypass list if it appeared on a claim no more than 5% of the time with packaged services. While the PRT did not run an analysis to verify this, we find it difficult to imagine that E/M codes 99213 and 99214 occurred less than 5% of the time with packaged services. The PRT would like to express caution about keeping these E/M codes on the bypass list, given that we typically provide both packaged services and other separately payable services when reporting CPT codes 99213 and 99214. Therefore, we urge CMS to remove these codes from the bypass list.

The PRT urges CMS to carefully consider add-on CPT codes and how they impact multiple procedure claims. For add-on CPT codes with SI "N", we recommend that the charges associated with the add-on CPT code first be packaged to the main CPT code so that the existence of two separately- payable APCs on the same claim with a packaged add-on code would not result in the claim being a multiple procedure claim. If the charges of the packaged add-on code are added to the main procedure code, then the remaining two APC payable services would be freed up as singleton claims. Therefore, by packaging charges associated with packaged add-on codes to the associated main procedure codes, CMS will be able to use more claims.

With regard to add-on CPT codes with APC assignment, we urge CMS to check whether the main procedure CPT and the add-on CPT are the only APC-payable services along with packaged line items that cause the claim to be a multiple procedure claim. If so, we urge CMS to use the main procedure CPT and the add-on CPT as a pair and apportion the packaged charges between these codes so that a correctly coded claim will be used in setting future rates.

A list of all add-on codes can be found in Appendix D of the CPT book.

2. Packaged services

The PRT would like to thank CMS and the APC Advisory Panel for the work they have done in reviewing codes with a packaged status indicator, particularly for services that may be the sole service rendered during an encounter.

First, we concur with the proposal to move bladder catheterization codes into separately payable APCs. Likewise, we thank CMS and the Panel for assigning APCs to vaccine administration CPT codes. These are excellent steps forward and we encourage both CMS and the APC Advisory Panel's Subcommittee on Packaging to continue reviewing other packaged codes that may warrant separate payment, either through an APC payment or through the use of the newly

proposed status indicator "Q". To that end, and in response to the APC Panel's request for additional detail, the PRT offers the following recommendations to CMS on several codes that we believe warrant separate payment, particularly when they are the only service provided to a Medicare outpatient in the hospital setting.

The PRT urges CMS to change the status indicators for the following codes for 2006:

A. Non-selective Debridement CPT 97602. This code, introduced by CMS in January 2001, has a long and arduous history under OPPS. The description of the code is: "removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session."

From the outset, CMS assigned status indicator "N" for packaged services to this code. The rationale was not published until Transmittal A-02-129, in which CMS states: "CPT code 97601 is a physical therapy service and is paid under the Medicare Physician Fee Schedule. Payment for CPT code 97602 is recognized under the OPPS as a packaged service (i.e., the service is not separately paid under OPPS); however, the cost of the service is packaged into whatever other service is provided on that date. It is common for 97602 to be performed at the time of another physical therapy service in which case payment for 97602 is packaged into payment for the other physical therapy service. If a service coded under 97602 is performed at the time of a clinic or emergency visit, the E/M service must be documented in accordance with the hospital's documentation guidelines for clinic and emergency visits. If the only service provided to a beneficiary is 97602, the hospital may bill outpatient visit code 99211. Payment for 97602 will be packaged into the payment for 99211. If a hospital provides and bills for 97601 or 97602 and a clinic or emergency department visit, the clinic or emergency visit must be separately identifiable and documented in accordance with the hospital's guidelines for documenting clinic and emergency visits."

CMS views these codes as physical therapy codes. These codes are not merely physical therapy codes, but also registered nurse codes. In fact, PRT providers report that registered nurses perform more wound management care in hospital settings than therapy providers. Physicians order patients to come to the hospital for wound care management services. Non-selective debridement is the only service the patient receives.

CPT Assistant gives an excellent example in their May 2002 issue: "A 70-year-old male who developed lower extremity ulcers as a result of venous insufficiency. The assessment reveals yellow necrotic tissue adherent to the wound base. The wound margin is undurated and inflamed. There is minimal clear serous drainage noted. It is determined that the patient would benefit from autolytic debridement. The wound and surrounding skin is lightly cleansed with a nontoxic cleanser. The wound is measured at 4.8cm x 3.1cm and the depth is undeterminable. An occlusive dressing (hydrocolloid/hydrogel) is then applied. The dressing is secured with a secondary dressing. The patient is instructed to inspect the bandage daily for break-through drainage."

This type of visit takes a nurse between 30-45 minutes to assess, make the dressing change, and then instruct the patient. The only procedure performed is non-selective debridement, which is reported with CPT code 97602 along with billable supplies. Since no other service was provided, hospital charging staff are reluctant to report another service, even though CMS has stated that CPT code 99211 can be reported in order to generate reimbursement for the packaged service. This is problematic, not only because this is not intuitive for staff charging for the services they have provided, but also because non-Medicare payers only want to see the CPT code reported for the service actually rendered. Forcing hospitals to report an E/M code to receive reimbursement is a round-about way for paying for the non-selective debridement service. In response to our having raised this issue last year, and again in February at the APC Advisory Panel meeting, CMS stated that this code has moved to the Physician Fee Schedule (MPFS) where in 2005 it has a status indicator of "B". This further hurts hospitals because now the code cannot even be reported. Language in the 2006 NPRM (on page 42962) states: "under the MPFS, a separate payment is never made for a 'bundled" service and, because of this designation, the provider does not receive separate payment for non-selective wound care described by CPT 97602. While this code now falls under the MPFS rules, payment policy for this 'bundled' service has not changed and separate payment is not made."

CMS does not appear to realize that this neither helps hospitals nor solves the fundamental problem. In fact, CMS has now placed hospitals in the terrible position of having medically necessary visits meet the definition of an outpatient encounter and providing covered outpatient hospital therapeutic services with no means of payment under either MPFS or OPPS – unless, of course, hospitals once again report CPT code 99211. Furthermore, hospitals are not allowed to render services to Medicare beneficiaries and simply not charge for those services, as this would raise a compliance issue.

The PRT urges CMS to carefully review the use of this code and discuss, with its own clinicians, what this service is and why it can (and does) occur as the only service provided to outpatients in the hospital setting. To facilitate CMS' review, we have provided CMS' own definitions of what constitutes a hospital outpatient, a hospital encounter, and how non-selective wound care meets the definition of coverage of outpatient therapeutic services under OPPS.

42 CFR 210.2 Defines Hospital Outpatient. *Outpatient* means a person who has not been admitted as an inpatient but who is registered on the hospital or Critical Access Hospital (CAH) records as an outpatient and receives services (rather than supplies alone) directly from the hospital or CAH. *Non-selective wound care patients are registered outpatients of the hospital.*

42 CFR 210.2 Defines Outpatient Hospital Encounter. *Encounter* means a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient. *The nurse or therapist has*

direct personal contact with the patient to treat the patient. This falls under scope of practice laws for nurses and also therapists. Medical staff physicians order wound care services from the nurse or therapist on behalf of their patient that they are managing in their offices. Wound care nurses and therapists report the care back to the ordering physician.

Publication 100-02, Chapter 6. Section 20.4.1 - Coverage of Outpatient Therapeutic Services. Therapeutic services which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians in the treatment of patients. Such services include clinic services and emergency room services. *Non-selective wound care patients meet the definition of covered outpatient therapeutic hospital services.*

Non-selective wound debridement will continue to be provided to Medicare outpatients in the hospital setting under OPPS. If CMS does not provide separate payment for this when it is the only service rendered, then hospitals who understand CMS' guidance will continue to be forced to report CPT code 99211. Others may not even charge for the service since it has a status indicator "A" under OPPS, but under the MPFS it has a status indicator "B" resulting in no separate payment.

Therefore, the PRT strongly urges CMS to assign the newly proposed status indicator "Q" to CPT code 97602 so that separate payment can be made when this is the only payable service provided under OPPS. The OCE can package payment for 97602 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

B. Collect Blood Venous Device 36540. CMS continues to assign this code a status indicator "N". Physician's offices often order patients to go to a hospital for blood work in cases where the patient has a venous access device. Drawing blood for lab work from a venous device requires that a registered nurse assess the patient, and then use a sterile kit with a needle to access the device, draw the blood, and flush the port afterwards to ensure patency. It typically takes 15-20 minutes to perform this procedure. This is a much more resource-intensive service than a simple venipuncture, yet venipuncture is paid separately under the Clinical Lab Fee Schedule, while CPT code 36540 is considered packaged.

Again, hospitals will only receive reimbursement for this service when it is the sole service provided if they report an E/M visit code. As stated above, this is not intuitive for the individual charging for these services. Moreover, private payers only want the hospital to report the actual service provided -- in this case, CPT code 36540 and not the E/M code. If CPT code 36540 remains packaged under OPPS with status indicator "N", then many hospitals will just report the E/M code 99211 instead of 36540. They will do so because it is extremely difficult to take a single service and break it into two charges (99211 and 36540) just to report that 36540 was the only service rendered. For this reason, CMS will lack accurate data on 36540. Furthermore, claims with 99211 represent a myriad of services, not just low-level clinic visits.

Therefore, the PRT strongly urges CMS to assign the newly proposed status indicator "Q" to CPT code 36540 so that separate payment can be made when this is the only payable service provided under OPPS. The OCE can package payment for 36540 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

C. Withdrawal of Arterial Blood 36600. CMS continues to assign this code a status indicator "N". Similar to the comment above about separate payment being made for a simple venipuncture, we do not understand why CMS will not make separate payment for an arterial blood draw -- which requires more effort and carries more risk to the patient than a simple venipuncture. This code is reported when blood is drawn from an artery for diagnostic purposes – most often as a means of drawing Arterial Blood Gases. Currently, CMS reimburses for the ABG, but not the arterial stick. It is possible to attempt to draw arterial blood and not be successful. Arterial sticks require specialized training to perform.

The PRT strongly urges CMS to assign the newly proposed status indicator "Q" to CPT code 36600 so that separate payment can be made when this is the only payable service provided under OPPS. The OCE can package payment for 36600 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

D. Injection Procedure for Sentinel Node ID 38792. This X-ray injection code, like others such as CPT code 42550, are assigned status indicator "N" and separate reimbursement is not made for them. The PRT agrees that separate reimbursement should not be made for these injection codes when they are provided along with a separately payable procedure APC. Cases exist, however, when the injection is the only service provided -- particularly when the procedure cannot be completed due to the patient having a reaction to the injection and no X-ray was taken, or where the injection is provided by the hospital outpatient department and the procedure provided by a different facility/provider. In such admittedly infrequent cases, hospitals should be able to recoup reimbursement for these services without being forced to report the entire procedure with a modifier -52 for reduced services. In fact, if providers report the actual procedure, CMS will make greater payments than it would if CMS simply paid for the injection procedure itself.

Therefore, the PRT strongly urges CMS to assign the newly proposed status indicator "Q" to CPT code 38792 so that separate payment can be made when this is the only payable service provided under OPPS. The OCE can package payment for 38792 when there is another APC-payable service on the claim, but can generate a separate APC payment using the same rate as proposed for Level I injection codes when this is the only billed service.

E. Irrigation of implanted venous access device for drug delivery systems – (expected 2006 CPT code 96523). Irrigation of implanted venous access device for drug delivery systems – (expected 2006 CPT code 96523). In Table 27, page 42739, CMS proposes to assign this new service/code a status indicator "N". The PRT cautions CMS against doing this, since occasions exist when irrigation of an implanted venous access device is the only service rendered to hospital outpatients. If this service is not separately payable, then hospitals will be faced with the problem of having to report an E/M visit code in order to receive payment. CMS should understand that private practice physicians often send patients to the hospital with an order to "flush the venous access device". Under this order, a Registered Nurse assesses the patient and the device. A sterile kit with sterile needle is used to access the device to ascertain whether the device is patent by receiving blood flow with aspiration and flushing of the device. In the instance of a new device, there is additional time spent to remove the original dressing and redress the site. If allowed to go untreated, these conditions could lead to more invasive and expensive procedures, including removal of the existing device and implantation of a new device. This service would not be expected to generate separate reimbursement when it is provided on the same day as other services such as IV infusion therapy, IV push medications, blood transfusions, or blood draws. In fact, it is likely that this service will be a component NCCI edit to the above procedures and will not be able to be reported or billed when the other services are provided. Currently, hospitals must report the flush service when it is the only service provided during the visit with an E/M code in order to receive payment for the resources expended.

We appreciate the new code for this service and urge CMS to assign the newly proposed status indicator "Q" to CPT code 96523 so that separate payment can be made when this is the only payable service provided under OPPS. The OCE can package payment for 96523 when there is another APC-payable service on the claim, and generate a separate APC payment, using the same payment assigned to APC 600.

The PRT urges CMS to assign the following packaged codes to a specific APC for payment:

A. Fluoroscopy Greater than One Hour 76001. Hospitals should be able to report fluoro over one hour and receive separate reimbursement for this service, since it takes more time and resources than are required for fluoro under one hour (which is represented by CPT code 76000). CPT code 76001 initially started as "N" status, then was changed to "S" status and paid, then changed back to "N" again. There are a small number of cases in which fluoro is required for over an hour, and hospitals should receive separate reimbursement for this service to cover the resources they have expended. CPT 76001 is not an add-on code. A fluoroscopy procedure is either under one hour (and the provider reports 76000) or over one hour (and the provider reports 76001). Therefore, the PRT urges CMS to change the status indicator of CPT code 76001 from "N" to "X" and assign it to APC 0272.

B. Bladder Catheterization for Specimen P9612. In keeping with CMS' excellent decision to separately pay for bladder catheterizations under OPPS, the PRT urges CMS to do the same for CPT code P9612. This procedure occurs in the Emergency and other

Departments when the patient is unable to perform the steps necessary for a "clean catch" sample and the nurse catheterizes to obtain a clean urine sample for clinical lab testing. This service requires the same level of effort and resource use as CPT code 51701. Therefore, the PRT urges CMS to treat it in the same manner as CPT code 51701 by assigning it to APC 0340 and making separate payment for this service.

C. Placement of occlusive device G0269. HCPCS code G0269 is a procedure which has a specific device associated with it. CMS has packaged both the procedure code G0269 and the device C-code (C1760) into endovascular APCs. This makes an assumption that this device and procedure are performed 100% of the time with other endovascular procedures. The reality is that this is one option for sealing the entrance site at the conclusion of an endovascular procedure. The PRT believes that payment would be more accurate to allow separate payment for the G0269. The PRT also believes that G0269 should be classified as a device-dependent APC, requiring the reporting of both G0269 and C1760 on the claim. C1760 would be appropriately packaged into G0269. This would enable CMS to create an edit for claims so that G0269 and C1760 must both be reported and paid separately through an APC payment.

D. Continuous Overnight Oximetry Monitoring 94762. The PRT recommends that the status indicator for CPT code 94762 -- Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure) -- be changed from "N" for packaged service to "X" and assigned to APC 0369 (Level III Pulmonary Tests).

Overnight Pulse Oximetry (94762) is indicated when the patient has a condition for which intermittent arterial blood gas sampling, or intermittent pulse oximetry measurement, is likely to miss important variations (e.g., sleep apnea); or when the patient has a chronic condition resulting in hypoxemia and there is a need to assess supplemental oxygen requirements and/or a therapeutic regimen. Medical literature indicates that identification of hypoxic patients in chronic obstructive pulmonary disease is important because there is a demonstrated survival benefit from long-term oxygen therapy (LTOT) in these patients.

Patients suffering from hypoxemia may experience different levels of oxygen desaturation while resting versus exertion and at night. Resting or single determinations of oxygen saturation via pulse oximetry or via arterial blood gases are the standard methods of making a determination of need for LTOT. A single measurement will not measure the patient's oxygenation during sleep or during daily living activities, however. Patients who would truly benefit from oxygen therapy may be missed if a single determination indicates an adequate SaO2 at rest or if, during a short walk, the patient is able to maintain a SaO2 that fails to meet medical necessity for oxygen therapy. Conversely, single determinations may identify a brief drop in PaO2 which falsely indicates a need for oxygen therapy and thereby increases CMS expenditures for oxygen therapy.

For patients with symptoms of suspected sleep apnea, continuous measurement during a period of sleep would be instrumental to the diagnosis of the patient's problem.

Polysomnography is a more complex and expensive test that is often used to diagnose sleep apnea. The polysomnography codes are currently assigned to APC 0209 and reimbursed at $661.97. Overnight pulse oximetry can be administered at a lower cost to rule out hypoxia during sleep, and avoid the more expensive testing for many patients.

When pulse oximetry is the only service provided to a patient in the outpatient setting, hospitals must report an E/M service in order to receive payment. Under OPPS rules, provision of this service has shifted to other settings. Physician clinics receive reimbursement for oximetry testing but usually do not have the hours of operation and resources to conduct overnight testing. This leaves testing in the patient's home as the only other option. To obtain valid test results in this setting, however, the patient must understand how to set-up and perform the procedure and must correctly follow through with it. It is not uncommon for poor or unusable results to be obtained via at-home testing, which leads to repeat testing and frustration for both the patient and family.

Assigning 94762 to a payable APC would accomplish two things. It would allow hospitals to provide a valuable service with appropriate reimbursement, and would potentially decrease the amount of money CMS expends for assessments for oxygen therapy and evaluation of patients with sleep apnea. With a proposed payment for 2006 of $162.58, APC 0369 includes other procedures with similar resource intensity (94070, 94621, and 94772) and would be an appropriate assignment for 94762.

Therefore, the PRT strongly urges CMS to assign CPT code 94762 to APC 0369 for 2006.

3. Two-times rule

CMS proposes to move CPT codes 75820 and 75822 from APC 0281 to APC 0668, and to move CPT code 75790 to APC 279. The PRT does not understand why CMS did not propose assigning all three CPT codes to the same APC -- APC 0279 – since the resources required to perform all three are similar for the following reasons:

1. The supplies required to perform the services described by CPT codes 75820, 75822, and 75790 are similar. All three require the use of guidewires, catheters, local anesthetic, and contrast.
2. CPT code 75822 is a bilateral procedure; hence, the supplies required and the overall resource use is greater since two different sites are accessed in order to perform the procedure. For this reason, it does not make sense to move CPT 75822 to APC 0668, as APC 0668 has a lower payment rate than APC 0279, the more appropriate APC.
3. CPT code 75658 (which is already in APC 279) is similar to CPT codes 75820, 75822, and 75790. The only difference is whether a vein is accessed versus an artery in an extremity.

For these reasons, the PRT respectfully requests that CMS move CPT codes 75820, 75822, and 75790, to APC 0279. For clarity, we also recommend that CMS change the title of APC 0668: "Level I Angiography and Venography except Extremity" to exclude language referring to extremities since none of the other CPT codes assigned to this APC relate to extremities.

4. New Technology APC

The PRT has two concerns with respect to the smoking cessation codes G0375 and G0376. Our first concern has to do with why the codes are assigned to New Technology APCs, given that smoking cessation counseling is not a "New Technology" and there are other, existing, APCs to which the codes could be assigned. The second has to do with CMS' proposed payment reduction resulting from moving these codes from their current New Technology APC placement with payment a rate of $25.00 to two lower-paying APCs. The lower payment rate will neither support hospital programs to provide the counseling services nor encourage separate reporting of smoking cessation counseling for tracking purposes.

In the document, "Process and Information Required for a New Technology Ambulatory Payment Classification (APC) Designation Under the Hospital Outpatient Prospective Payment System (OPPS)", posted on the CMS HOPPS web page with an effective date of July 26, 2005, CMS indicates the following criteria for a service to be eligible for a new technology APC:

- The service is one that could not have been adequately represented in the claims data being used for the most current annual OPPS payment update.
- The service does not qualify for an additional payment under the transitional pass-through provisions established under section 1833(t)(6) of the Social Security Act and in Subpart G, Transitional Pass-through Payments in the regulations at 42 CFR 419.
- **The service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs.**
- The service falls within the scope of Medicare benefits under section 1832(a) of the Act.
- The service is determined to be reasonable and necessary in accordance with section 1862(a)(1)(A) of the Social Security Act.

The Smoking Cessation codes G0375 and G0376 are defined as counseling services with the word "visit" as part of the codes' descriptions. Counseling is generally considered part of the provider's evaluation and management service; indeed, information published on the new smoking cessation codes (Transmittals 36 and 562) indicates that smoking cessation counseling provided for less than three minutes is: "bundled into the normal evaluation and management visit". In a hospital facility, the service will be provided in an outpatient department as a clinic visit subsequent to an order by the patient's physician. The resources required to provide smoking cessation counseling are similar to those required for a facility low-level clinic visit. This means both G0375 and G0376 can "reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs", making the New Technology APCs an inappropriate assignment for these codes. The PRT recommends that CMS assign HCPCS codes G0375 and G0376 to APC 0600 instead of to the proposed New Technology APCs.

Not only does the assignment of these codes to a clinic visit APC make more sense, but it also will result in more adequate reimbursement for the services. Following work conducted by the Medicare Healthy Aging Initiative, the smoking cessation counseling codes were developed to encourage physician and hospital providers to offer counseling for smoking cessation and to allow CMS to separately track the services for frequency and effectiveness. The new codes were implemented in March of 2005 with a reimbursement rate of $25.00. Even at this below-cost reimbursement, hospitals began to develop business plans and made decisions to offer the new smoking cessation service because clinicians agree that smoking cessation is important for Medicare beneficiaries that smoke. If the lower payment rates proposed in the 2006 OPPS rule are finalized, CMS may see smoking cessation counseling provided primarily in the physician's office rather than the hospital outpatient setting. CMS should set reimbursement at a level that allows hospitals to support this important service and encourages them to separately report G0375 and G0376 for tracking purposes. Therefore, the PRT urges CMS to assign both G0375 and G0376 to APC 600 for a low-level clinic visit.

If CMS does not accept the above recommendation, then CMS must clarify the final payment rates and assignment of G0375 and G0376, since Table 10 and Addendum B are inconsistent and show different payment rates for the codes. Table 10 shows HCPCS code G0375 assigned to APC 1491 with a payment rate of $5.00 and G0376 assigned to APC 1492 with a payment rate of $15.00. Addendum B shows both codes assigned to APC 1491; the APC with the lesser payment rate of $5.00.

Stereotactic radiosurgery (Cobalt-60)

The PRT is concerned about CMS' proposal to combine Cobalt 60-based SRS planning and treatment delivery codes G0242 and G0243 respectively. These are two separate services and modalities and should be considered as such. Combining these two codes deviates from the general standard of practice, currently in place for charging Radiation Oncology services, in which the plan of the treatment and the actual delivery of the treatment are separately charged.

Combining the planning service with the actual treatment delivery assumes two things. First, that the plan is the same each time; in reality the plan is different based on the diagnosis, the number of lesions being treated, and the size and location of each lesion. In other words, two patients that both have one lesion may not have the same plan: one lesion could require two shots to treat due to its size, while the other could require a greater number of shots. The planning phase is often quite intricate and time-consuming, and must be done with great care, since one dose of gamma radiation could be lethal.

The second, and perhaps the more important, reason why the two codes should not be combined is because there are instances in which planning occurs but the treatment is not provided. Radiation Oncologists at one of the PRT hospitals stated that: "a treatment cannot be provided without the plan, but the plan can be provided/created without the treatment ever being delivered". If the two codes are combined, CMS may end up overpaying if a payment is made using the code for the day the plan is created as well as the day the treatment is delivered (only in cases when both are not provided on the same day). A more likely scenario is that CMS will end

up requiring hospitals to report modifier -52 with the code when the plan is created but the treatment is not delivered. While this can be done, CMS will still pay 100% of the procedure payment rate and when the same code is billed again on the day of treatment, CMS will again make 100% of the APC payment unless some sort of special cross-claim logic is created in the APC to find such claims so that no overpayments are made.

Sometimes, after the patient has been framed and the MRI scan has been accomplished, problems arise that result in the actual treatment being delayed. Examples include when a lesion is outside of the framed area, or multiple lesions appear from the initial MRI scan. In these instances, additional planning is necessary to adequately treat the additional areas. Under the proposed rule, the only billable item is the planning with the delivery reported on the day of the actual treatment delivery. Without separate codes, CMS might end up reimbursing for both services (since they will occur on different days) and making double payment. CMS might require hospitals to report modifier –52 in these cases but, since reimbursement is still being made at 100%, providers would again receive full payment on both the planning day and the treatment delivery day. This becomes a problem administratively because of the adjustments that need to be made "behind the scenes" to reduce charges and to make sure the modifier is attached.

Finally, it should come as no surprise to CMS that hospitals have been confused about reporting these codes as well as the planning code for linear accelerator-based SRS (G0338) since CY 2004. For this reason, CMS should proceed carefully in its use of the 2004 claims data to set 2006 payment rates. The PRT believes that, by keeping things as they are for one more year, CMS will be more likely to collect reliable data for use in setting 2008 payment rates.

The PRT also understands that CMS has requested comments on the use of existing CPT codes instead of the planning and treatment delivery G-codes for Cobalt-based SRS. While this will be another change in Radiation Oncology coding/billing, the PRT favors this proposal over combining planning and treatment into one code, as the codes for planning and treatment are currently separate in the CPT.

5. Device-Dependent APCs

Over the past several years CMS has employed a variety of methodologies to set rates for device-dependent APCs, and those methodologies have changed from year to year. This has been necessitated because providers have historically not appropriately reported charges and codes for procedures and devices, based on whatever reporting mandate was in place. By using 2004 claims data, CMS faces the obstacle of setting 2006 payments without complete and accurate information for device-dependent APCs.

Since the reporting of reinstated device HCPCS codes was optional in 2004, most providers had no sense of urgency in accurately reporting the codes. Thus, CMS does not have adequate data to use in creating the payment rates for device-dependent APCs for 2006. CMS has proposed using all single bills using claims data both with and without C-codes in setting APC rates, and has proposed to limit the downward adjustment to 85% of CY 2005 payment rates. The PRT does not believe this is enough of an adjustment, however, given that the incorrectly reported claims

data are similar to the situation that occurred in 2005, when no device coding existed because the codes had been deactivated.

The PRT recommends that CMS freeze payment rates for device-dependent APCs in 2006 at the current 2005 payment rates. This will minimize the instability providers have experienced with the payment rates over the past several years. Furthermore, by freezing the payment rates at the 2005 level, CMS may prevent even greater payment rate fluctuation in 2007 when device C-coded claims data from 2005 are used to set payment rates. We believe the 2007 median cost data for device dependent APCs will be more similar to the current 2005 payment rates than to the ones proposed for 2006, even with the proposed 15% dampening.

At an absolute minimum, if CMS does not freeze the rate, the PRT urges CMS to employ the methodology used for this year's device-dependent OPPS payment rates: to limit the adjustment of 2006 median calculations to 95% of the CY 2005 OPPS payment median, resulting in only a 5% payment decrease.

Finally, the PRT does not believe CMS is using claims data with device C-codes with a nominal line item charge (i.e., $1.00) to set payments; nor do we believe these claims should be used to create median costs and APC relative weights. In the final rule, we ask that CMS confirm that line items with a nominal charge were not used to set median costs.

Claims subject to a device recall should also not be used to develop median costs and relative weights, as these line items presumably also carry a nominal charge. CMS may need to provide clear guidance on how providers should not report devices recalled on the claim form using a special condition code or a value code. This would enable claims with the condition or value codes to be isolated for review and exclusion from the rate-setting process.

The PRT believes that CMS erred when it stopped making separate payment for high-cost devices and instead packaged the "costs" into the related procedure APC, thus providing payment for both the device and the procedure through one APC payment. As CMS is aware, providers are not perfect in reporting items that do not generate separate payment. Unless the majority of hospitals are diligent about reporting all of their services (including packaged services) accurately and completely, payment rates will not reflect the data reported by those providers that do report correctly, since the data are averaged together. If CMS paid for high-cost devices separately, it would certainly receive accurate and complete data. Since the majority of devices are packaged, and since reporting them has been optional, the claims data remain incomplete and inconsistent.

The PRT urges CMS to review the concept of paying for high-cost devices separately rather than "packaging" the costs into the procedure payment rate. A standard definition of high-cost devices would need to be created, and we recommend defining high-cost devices as those with a cost greater than 50% of the APC payment rate.

6. Pass-Through Device Categories

The PRT would like to thank CMS for soliciting providers' input regarding devices. The questions CMS asked were well thought-out and concise. We whole-heartedly support the inclusion of natural orifices as an opening when defining a device. This change will allow non-invasive technology to continue to grow.

In addition, this definition will be much easier for both those charging for the services at the point of care and coding staff to understand and operationalize. This is a positive change for both providers and beneficiaries; the PRT appreciates the detailed discussion provided in the proposed rule.

7. Drugs

The PRT understands that CMS' has proposed to pay for all separately payable drugs (except new drugs without HCPCS codes) using average sales price (ASP) plus 6%, which is similar to estimates in the physician office setting of "average acquisition cost". In addition, CMS proposes to pay an additional 2% of ASP to cover the handling cost or pharmacy overhead component of drug payments. Both components are reflected in the drug APC payment rates as published in Addendum B of the 2006 OPPS proposed rule.

The PRT has concerns about the proposal to pay an additional 2% of ASP for handling costs and CMS' proposal that hospitals will be required to report new drug handling C-codes starting January 1, 2006 in order to capture drug handling charge data which CMS may use to create separate drug handling APCs in the future.

Before we detail our concerns about these two issues, the PRT offers the following comments about brand vs. generic codes, payment for new drugs without HCPCS codes, determining how to package drugs in the future, and IVIG.

Brand vs. Generic

By using the ASP model, CMS no longer needs to collect brand vs. generic drug data and has, therefore, proposed to eliminate the use of the brand name drug C-codes. The PRT strongly supports the recommendation to eliminate these codes, as it will simplify how providers charge for brand and generic drugs. The PRT requests, however, that CMS clarify how it determines the average sales price used to reflect payment for both brand and generic drugs since the drugs available for purchase vary. The PRT seeks clarification about whether CMS has taken an average price based on the volume of brand vs. generic drugs purchased by providers during a given quarter.

New Drugs Without HCPCS codes

The PRT supports CMS' continued method for paying for all new drugs without HCPCS codes using C9399 and the rules published in the May 28, 2004 Transmittal 188, Change Request 3287, for reporting new drugs without HCPCS codes.

Non-Pass-Through Drugs (determining how to set a threshold for packaged drugs in the future)

The PRT understands that CMS has requested comments on how to package drugs starting in 2007. The PRT appreciates the opportunity to comment and strongly believes CMS should provide separate payment for all infused and injectible drugs regardless of the "per day median" cost, and only continue to package oral drugs. This approach would create consistency in payment policy between the hospital and physician settings. CMS has already begun this process by aligning payment for many separately payable drugs this year (and even more so in 2006), as well as by proposing to require the same drug administration CPT codes in both settings starting in 2006.

The PRT believes that CMS cannot intend to create consistency in some areas while leaving large differentials in others. For example, physicians receive higher payments for drug administration services and are paid for multiple administrations and hours of infusion service; hospitals are not. There are, of course, reasons for this differential, based on the lack of hospital data, but this lack is expected to be eliminated as CMS collects more data from hospitals in the future. In other areas, such as drug packaging, there is no shortage of data and CMS should align payment policies and incentives so that physicians and hospitals are treated equitably beginning in 2007.

Therefore, the PRT recommends that CMS pay separately for all infused and injectible drugs, most of which, we believe, have a HCPCS code.

Intravenous Immune Globulin (IVIG)

In April 2005, CMS eliminated two existing immune globulin (IVIG) HCPC codes (J1563 and J1564) and replaced them with four new "Q" codes. The new Q-codes are still based on 1gram and 10mg dosages, but distinguish between lyophilized and non-lyophilized forms of IVIG. The payment rates for the four new codes are the same regardless of formulation, and remain similar to the payment rates released for the J-codes in January 2005. Both the 1g codes have a payment rate of $80.68 while the 10mg codes have a payment rate of $.75. The PRT does not understand why CMS made this change given the additional burden such changes place on providers.

Other payers may not recognize the different codes used by CMS, forcing providers to maintain separate charges for both codes in their CDMs based on payer type. Providers also have to manually change the billed codes into codes recognized by non-CMS payers in order to bill secondary insurers for the patient's Medicare co-pay.

In addition, it is not clear why the new codes distinguish between lyophilized and non-lyophilized IVIG. Given the shortages of IVIG, hospital pharmacies purchase whichever version is available in order to supply it to patients. In fact, pharmacy staff cannot ensure a consistent inventory of IVIG and must physically check their inventory to identify which drug form is in on the shelf before putting a charge in the computer.

While changes in 2005 have led to operational problems such as those described above, the issue for 2006 is expected to be worse given the proposed payment rate reductions for IVIG. In 2006,

CMS proposes different payment rates for each of the four IVIG codes, and decreases in payment rates ranging from 24% to 51%. Such reductions are unacceptable, given patients' need for IVIG. The PRT strongly urges CMS to revert to its original J-codes and maintain IVIG payment rates at the January 2005 level.

2006 Proposed Drug Payment Rate Methodology

The PRT has no fundamental problem with CMS' use of ASP+6% to set the average acquisition cost. We are concerned, however, about CMS's proposal to reimburse providers' handling costs and overhead expenses at 2% of ASP. Given that MedPAC found that pharmacy handling costs represent 26% to 28% of the total cost of providing drugs, it seems unreasonable for CMS to allocate just a fraction of that estimate to the drug payment rate to cover hospital handling costs/overhead expenses.

The PRT understands that CMS reviewed three different data sets to generate the final proposal for reimbursing separately payable drugs in 2006. On page 42725, CMS states that it compared the following: 1) GAO acquisition data for 55 separately payable drugs accounting for 86% of Medicare spending for specified covered outpatient drugs; 2) ASP data from 475 drugs payable under OPPS (CMS does not include the percentage of payment these drugs constitute); and 3) mean cost data from calendar year (CY) 2004 claims (which differs from the 'median' cost calculation used in all prior years of OPPS rule-making).

From this comparison, CMS determined that ASP+8% would cover both the average acquisition cost (ASP+6%) and pharmacy handing (ASP+2%), which appears to be over-simplistic. The PRT assumes that CMS did not calculate the impact of using a 'median cost' from CY 2004 claims on the 2006 proposed payment rates. CMS has arguably accounted for drug handling and overhead in the 'median' cost payments for these drugs, yet CMS proposes to pay for them using 'mean' costs. The PRT requests that CMS conduct and release an impact estimate on the 2006 proposed payment rates, by drug, of the difference between using the "median cost" vs. the "mean cost" to come up with the ASP+6%+2% model.

The PRT's group of 18 providers estimated our individual pharmacy handling costs and found them to range from 28.71% to 133.11% of total pharmacy costs. In preparing our estimates we used cost report line numbers for both direct pharmacy costs (Worksheet B, Part 1, Column 0, Line 56) and indirect pharmacy costs (Worksheet B, Part 1, Column 27, Line 56 Less Worksheet B, Part 1, Column 0, Line 56). If PRT members can compute this simple analysis and quickly estimate our pharmacy handling costs as a percentage of total pharmacy cost, it should be feasible for CMS to conduct a similar analysis using cost report data from all hospitals. Despite the fact that the data would be two to three years old, CMS would nonetheless have another data source showing an estimate of average pharmacy handling costs as a percentage of total costs for all Medicare providers.

The PRT is challenged to create a recommendation that is fair and appropriate for estimating pharmacy handling costs, particularly in the short time since publication of the proposed rule. Despite the results from our own survey data, the PRT recognizes that it is unreasonable to ask CMS to increase ASP+2% to ASP+100% -- or even ASP+30% -- to cover pharmacy handling

costs. We strongly urge CMS to gather additional data and study this issue further. Therefore, we recommend that CMS simply dampen drug payment rates in 2006 so they are no lower than 95% of the current 2005 drug payment rates. CMS has done this with other APC services, and we believe it is appropriate for drug payment rates.

Capturing Drug Handling/Overhead Cost Data using C-codes in 2006

The PRT also wishes to comment on CMS' proposal to require hospitals to report one of the three newly proposed drug handling C-codes to reflect separate line item drug handling charges. The PRT wishes to describe the extremely serious financial and operational consequences that will result if CMS finalizes its proposal to require C-codes for drug handling charges for 2006.

Financial considerations

It is important for CMS to consider that Medicare providers must charge all payers in the same way. This is specified in Provider Reimbursement Manual (Publication 15, Part I, Chapter 22, §2204). It is impossible for providers to report a J-code drug to Medicare with a dollar amount that does not include handling costs, and a different (higher) charge to another payer using the same J-code. CMS seems to believe that other payers will follow its lead in separately recognizing and paying C-codes for drug handling -- but this is not necessarily true. In an environment of cost containment and cost pressures, private payers maximize their own best interest, even when this means being inconsistent with CMS. Many hospitals currently struggle with other payers to recognize some J-codes for drugs.

Even in the unlikely event that other payers follow CMS' lead, they will not all be ready on January 1, 2006, and a differential will exist from the beginning of the new process. Even if other payers accept both the HCPCS code for the drug, and a C-code for the handling charge, providers are likely to lose money if they are currently being paid on a percent of charges associated with the HCPCS drug code. In order to stay revenue neutral, therefore, hospitals would have to charge Medicare one (lower) charge for the J-code while charging a different (higher) charge to other payers. This is not allowable, however, as providers must bill consistently regardless of payer. Therefore, CMS should carefully consider how its new proposal to require drug handling C-codes will impact providers in general, and not just in terms of Medicare.

CMS should recognize that pharmacy handling costs are already built into the overall drug charge. For this reason, the use of special codes to capture only the handling charge will create additional work for providers. They are unlikely to report the codes accurately or set charges correctly since no separate/additional payment will be made for the use of these codes for the foreseeable future.

It appears that CMS expects providers to adjust the charge of each drug and then create new charges for each drug handling category. It is not clear if CMS expects the handling charge reported to only reflect the "handling effort/expense" of the pharmacist or total overhead for pharmacy. For example, proposed Category 2 includes "single IV solution/sterile preparation (adding a drug or drugs to a sterile IV solution)" and "compounded/reconstituted IV preparations (requiring calculations performed correctly and then compounded correctly)". A nurse can add a drug or drugs to a sterile IV solution; for example, mixing the pre-measured powder antibiotic

that is packaged in a vial connected to a small bag of IV fluid (e.g., Ancef). A licensed pharmacist handles all drugs that must be compounded or reconstituted, and calculated based on the patient's body weight (e.g., Adenosine). This requires precise calculations and formulations of the drugs to ensure that the correct dosage is administered. Where there is a difference in cost between the handling performed by a nurse and that performed by a pharmacist, it is not clear if hospitals are required to report a blended or average cost. Alternatively, CMS might expect hospitals to report the actual cost based on the discipline that handles the drug.

This is just one example of how hospitals will have to develop appropriate handling charges for each C-code. Hospitals will not reduce their charges for drugs, as this would cause havoc with hospital revenue. Any change in drug pricing will take careful planning and time, far more than is available between publication of the final rule and the codes' proposed implementation date on January 1, 2006.

Operational considerations (coding, billing and charging issues)

The proposed use of the drug handling C-codes also raises a number of operational questions that CMS must consider before moving forward with implementation. The PRT questions whether CMS expects multiple line items to be reported per date of service if multiple drugs from the same drug handling family are provided. Alternatively, CMS might expect that only one drug handling C-code from each category, as applicable, would be reported on a given date of service with multiple units of service if multiple drugs from the same category are administered.

It is also not clear whether CMS will require providers to report a single revenue code with the pharmacy handling C-codes, or whether the revenue codes will need to match the actual drug revenue code reported. If the revenue code has to match the drug revenue code, then providers will have to create multiple Charge Description Master line items; this will result in increased burden to maintain the CDM. For example, if CMS allows providers to report handling charges using revenue code 636, then only three charges (one for each handling C-code) would be added to the CDM. If providers have to report handling charges using the exact same revenue code as the drug HCPCS, however, many more line items will need to be added to the CDM (i.e., handling charges will need to be set up under revenue codes 250, 636, 637, 259, etc.). The latter process is cumbersome to build and maintain.

Claims processing systems allow reporting of items under revenue codes in one of two ways: either by rolling up all items into one line item that reflects the total quantity and total charge billed under that revenue code; or by reporting a detailed listing of charges on individual line items. The revenue code assignment will dictate whether the handling codes are rolled up into one line item with everything else reported in that revenue code, or detailed out on the claim in a single line item per C-code with multiple quantities on a particular date of service. Again, claims processing systems cannot summarize some line items and detail others if all are reported with the same revenue code. Depending on the revenue code(s) assigned for these handling codes, the claim could become very long and burdensome for both the provider and payers.

Another example of an operational concern involves whether the C-code charge can be generated automatically or if it will have to be added manually on the back end of the billing cycle. Many hospitals utilize point-of-service charging in areas such as the Emergency Room, outpatient

oncology units, PACU, etc. Medications in these areas are charged as they are ordered and administered. Requiring an additional charge to be entered for handling the medications will create a high compliance risk. First, many of these areas have secure systems (such as a Pyxis or Omnicell) for storing medications. When a medication is removed for administration, the charge is sent electronically from this system to the hospital's billing system. Adding a handling charge will require manual intervention, since these systems are not set up to assess an automated handling charge.

A sampling of other operational issues and questions related to the use of drug handling C-codes are listed below:

- If a physician's order states, "Demerol 50 mg and Phenergan 25mg to be given intramuscularly" and the nurse obtains a vial of Demerol and a vial of Phenergan and draws up the prescribed dosages into a single syringe, would CMS expect one or two handling charges to be reported? We believe that CMS expects a one-to-one relationship between the drug and the handling charge; therefore, in this scenario, two handling charges would be reported since both medications were obtained, prepared ("handled"), and injected.
- For drugs reported with a HCPCS code, is the handling charge reported per dose of the drug, per vial/amp of drug used, or per billing increment based on the HCPCS code description? Should additional units of the handling code be reported based on the number of administrations if small amounts of the drug are prepared to be given over a period of time? For example if the physician order states: "Percocet 1 or 2 tablets for pain", and the patient requests and receives two tablets, would the provider report one handling charge? If the patient requests only one tablet but later requests the second tablet, would the provider report one or two handling charges? Each of these options results in a different quantity being reported in the units of service field for the handling C-code line item.
- Will CMS create OCE edits requiring a one-to-one match between a drug HCPCS code and a drug handling C-code?
- When a drug is prepared but not administered to a patient, due to a change in condition or physician order, will providers be allowed to report the drug handling charge since resources were expended to prepare the drug? In other words, will CMS allow a handling charge to be reported without a corresponding drug HCPCS code? If CMS plans to edit using the OCE, it will be challenging unless providers are given explicit instructions on how to report handling charges for drugs that are prepared but not administered to the patient.
- Does CMS only expect providers to only report a handling charge for separately payable drugs?
- Will CMS make a handling payment for packaged drugs using ASP+2% or another model? How will CMS determine what this payment should be if the drugs are not reported with HCPCS?
- How does CMS define "handling" or "pharmacy overhead"? According to the MedPAC report, the dimensions of handling costs considered include: management, including

regulatory compliance; storage, including inventory management; preparation, including review of drug orders and dosage calculations; transport within the hospital; and disposal of products. Within each of those categories are labor, benefits, space, equipment, supplies, and support contracts (to provide services such as waste disposal). It is not clear where other costs should be reported, such as: hospital administration, human resources, information technology, continuing education, hospital housekeeping, utilities, interest expenses, and other costs not directly related to pharmacy but which are currently spread over all hospital departments

If CMS decides to move forward with the implementation of the drug handling C-codes despite these concerns, the PRT requests clarification on what status indicator CMS plans to assign to these codes.

Ultimately, the use of separate codes to capture pharmacy handling costs will only increase the operational burdens that hospitals face, and simultaneously increase their costs. The PRT urges CMS to review the coding and billing requirements necessary to implement such a mechanism correctly and to truly consider the data that might be received. Before proceeding with this proposal, the PRT believes CMS should study alternate mechanisms including using provider cost report data to determine the average drug handling percentage across all Medicare providers.

Therefore, the PRT recommends that CMS not implement the proposed drug handling C-codes in 2006. Instead, we recommend that CMS study alternate mechanisms for obtaining handling cost data, including using the cost report to compute an average pharmacy handling percentage that may be used in the future along with the ASP+6% model. We offer our specific thoughts on how CMS might use the cost report below.

The PRT believes CMS can use existing cost report data instead of requiring providers to report the drug handling C-codes. We believe that CMS has the needed worksheet/line item detail from the cost report but, if not, CMS can work with the Fiscal Intermediaries who do have it. Moreover, there is a precedent under OPPS for CMS to instruct its FIs to provide specific cost report calculation details to its providers to obtain specific data required by CMS and FIs and to make appropriate payments. Examples include the detailed guidance CMS released regarding calculation of the payment-to-cost ratio in the early years of OPPS and, more recently, the guidance related to calculating the outpatient cost-to-charge ratio. In both cases, providers were able to respond to their FIs who, in turn, use the data for payment purposes. We believe that CMS can use a similar method to obtain each provider's pharmacy handling percentage and urge CMS to conduct this exercise as soon as possible.

Several PRT members conducted such a calculation using 2004 fiscal year end Medicare cost report data. Both directly assigned pharmacy overhead expenses were identified plus "stepped down" indirect overhead expense. We do not expect CMS to use the calculated overhead percentage from one, two, or even 20 hospitals. We do believe, however, that CMS can conduct a similar analysis using cost report data from all hospitals, or provide explicit guidance to providers through the FIs that results in the uniform collection of the pharmacy overhead percentage from all providers.

We believe that CMS will receive many comments on this issue and that estimates of pharmacy overhead will range greatly. CMS should recognize that this is, in part, due to the different interpretations of pharmacy handling costs/overhead expenses. The PRT is concerned that the terminology used by CMS about "expenses above and beyond acquisition expense" may inadvertently lead to the exclusion of certain categories of legitimate overhead expenses. Conversely, it might inadvertently include direct expenses that are not handling/overhead expenses.

For example, the indirect expense of maintaining electronic medical records for medication administration records is crucial and valid as a pharmacy expense, especially given the Institute of Medicine initiatives to automate pharmacy drug dispensing to prevent errors. This is clearly a legitimate pharmacy handling or overhead expense. An example of another legitimate expense that should not be categorized as handling/overhead is a face-to-face pharmacist consultation with patients for medication therapy management. If CMS accepts the PRT recommendation, and provides instructions for FIs to use with providers to collect a pharmacy handling percentage estimate, the instructions should contain a comprehensive definition of what can and cannot be included in the estimate so that CMS will receive comparable data.

Self-Administered Drugs

Finally, the PRT requests CMS to clarify two issues related to requirements for reporting self-administered drugs. The first has to do with whether or not handling C-codes must be reported for these items, and if the costs will be considered non-covered similarly to the drugs themselves being non-covered. If the drug handling C-codes are non-covered, the PRT seeks clarification if CMS see this payment as being the beneficiary's responsibility.

Our second issue, with respect to self-administered drugs, concerns beneficiary questions that may arise from the new Part D coverage beginning on January 1, 2006. The Medicare Online Manual Publication 100-04, Chapter 1 Section 60 gives hospitals two choices for billing non-covered self-administered drugs: 1) bill A9270 with modifier -GY in the non-covered column of the claim with other covered services to communicate that this is a statutory non-covered charge for which the patient is liable; or 2) separate the non-covered charges onto a separate claim with condition code 21.

The UB-92 claim form will contain the same minimal drug detail regardless of which billing method the hospital chooses. Drug line-items will show the revenue code, the date of service, units of service, and the total charge for the line-item. There will be no specific detail related to the actual drug that was administered if HCPCS code A9270 is billed. Furthermore, when the denial is obtained from Medicare and the liability reported on the beneficiary's explanation of benefits (EOB), the statement that the hospital sends the beneficiary will not (as it does not today) contain any detail on the actual drug that was administered.

For example, a beneficiary has an outpatient visit and receives aspirin for pain and atenolol for high blood pressure. Both of these drugs are non-covered, self-administered drugs. The hospital chooses to submit these charges on a separate claim form (option 2, described above). The UB-92 claim form submitted to Medicare shows the following:

Revene Code	Revenue Code Description	Date of Service	Units	Charges
637	Pharmacy Self Administered	9/1/2005	4	$5.00

The beneficiary will receive a hospital statement showing the following:

Date	Service Description and Quantity	Total Amount
9/1/2005	Pharmacy Quantity 4	Amount $5.00

With the new Part D prescription drug benefit beginning January 1, 2006, patients will expect their prescription drugs to be covered. Indeed, CMS has confirmed that prescription drugs will be covered, with its statement on page 4268 of the January 28, 2005 Final Rule.

The PRT is struggling with how hospitals can help beneficiaries understand why they will continue to receive hospital statements and bills for prescription drug charges when the beneficiary has the new prescription drug Part D benefit and believes that their prescription drugs are covered under Part D. The PRT seeks guidance from CMS about how to respond to beneficiaries who want hospitals to help them apply for and receive Part D coverage for prescription drugs. The PRT is deeply concerned that beneficiaries will be confused about the new coverage process, and is interested in working with CMS to address these issues now so that the implementation of Part D is successful next year.

8. Vaccines and Vaccine Administration

The PRT appreciates CMS' proposed changes for vaccines and vaccine administration and urges CMS to make these changes final. The status indicator changes proposed for influenza and pneumococcal vaccines will greatly aid with immunizations provided in emergency room settings. We would like CMS to clarify, however, that the status indicator change for HCPCS codes G0008 and G0009 will not impact our current method of roster billing for these vaccines when administered in hospital outpatient departments. We do not believe this is the case, but would appreciate CMS clarifying this in the final rule.

In addition, the PRT strongly supports CMS' proposal to pay separately for vaccine administration services -- as shown in Table 28 – and urges CMS to make these changes final for 2006.

The PRT would like CMS to clarify what we believe to be a typo in the middle column of page 42739. We believe CMS intends for hospitals to report administration of the hepatitis B vaccine using codes 90741 and 90742, rather than codes 96471 and 96472 as listed in the proposed rule.

9. Drug Administration

Last year, the PRT supported CMS' proposal to require providers to use CPT codes to report drug administration services, as this would ease the operational burden of reporting Q-codes to Medicare and CPT codes to other payers. CMS proposes to continue requiring hospitals to report CPT codes, and the PRT continues to support that process, in principle. The new 2006 drug administration CPT codes are, however, fundamentally different from the current 2005 CPT codes in the number of codes available, the description of the codes, the logic behind the codes, and the narrative CPT text providing guidance on how to use the codes. As a result of these differences, hospitals face an exponentially greater challenge in implementing the new codes and rules than they did when the change was made from Q-codes to 2005 CPT codes.

CMS stated that it could not release the actual 2006 CPT codes and descriptions because they were unavailable. Instead, CMS has released the expected descriptions of these codes, based on the temporary HCPCS G-codes that physicians use in their private practice settings. The PRT thanks the AMA for responding to requests to release an advance copy of the 2006 CPT drug administration codes and descriptions, which enabled providers to review the actual codes as part of the formal OPPS comment period.

The PRT understands that, although many more codes will be required for reporting drug administration services, CMS still intends to pay hospitals under OPPS on a "per visit" basis, as is done today. This means that hospitals will bill all of the relevant CPT codes that correspond to the services provided. But, payment will continue to be limited by the OCE's collapse of multiple billed services that group into the same APC into a single APC payment, unless modifier -59 is present to indicate that a separate encounter occurred on the same date of service. CMS must continue to make "per visit" payments for another year, as it lacks CPT code-level data upon which to base more refined drug administration payment rates. CMS should recognize, however, that the 2006 CPT book includes many more drug administration codes, and that the new codes and descriptions are completely different in their "logic". This means that providers will need to receive comprehensive and detailed guidance from CMS, along with clinical examples and plenty of time, if they are to adapt to the new codes and rules.

Before proceeding with our specific recommendations related to the use of the 2006 drug administration codes, the PRT reminds CMS that drug administration services are generally assigned ("charged") at the departmental level or at the point of service. Thus, drug administration CPT codes are embedded in the Charge Description Master (CDM) and departmental staff (often clinical staff) are responsible for charging the appropriate codes based on the services provided to the patient under their care. Drug administration services typically are not coded by Health Information Management/Medical Records or individual coders, and this change cannot easily be made, given the shortage of coding staff and the increased delay in submitting claims to Medicare likely to result if drug administration services also have to be coded by HIM/Medical Records staff.

To that end, the PRT asks CMS to consider the following very carefully:

- The new CPT codes were created at the 11th hour last summer and converted to temporary G-codes for use in the physician setting in 2005. The G codes were created to provide physicians with a way to bill for each and every instance, or combination, of drug administration service(s) provided, to off-set the significant drug payment decreases required by the Medicare Modernization Act (MMA). Physicians in their private settings receive payment for almost every single G-code today and, hence, will receive payment for every 2006 CPT code billed. Furthermore, physicians receive separate payment for each drug administered. This is not the case in the hospital setting.

- CMS must recognize that "one size does not fit all" when it comes to the use of CPT codes. We have seen this discrepancy with many different codes including the conscious sedation bulls-eye codes in Addendum I, evaluation and management codes, critical care codes, modifiers and others. CMS has been forced to provide separate guidance to hospitals on how to "interpret", "use", and even "ignore" certain CPT codes (or parts of the CPT description) because the codes are not applicable in the hospital setting. The PRT asks CMS to keep this history in mind as it reviews our comments and recommendations below.

- It will be virtually impossible for hospitals to implement separate codes for initial, subsequent, and concurrent injections and infusions, since patients "flow" through hospitals in a way that is fundamentally different from how they are treated in a physician's private setting. In hospitals, which operate on a 24-hour basis, patients often move from one care area, or department, to another; charges are commonly entered by each department in "real-time", without the departments necessarily knowing what services other departments have already charged. The concept of "initial" as the primary reason for the visit is impossible to automate using the CDM.

- The new codes and descriptions are not intuitive, and will be a nightmare for clinical and coding staff to accept. One example is the concept of only reporting one "initial" service code, where initial means the "primary reason for the visit". A second example is reporting an additional hours' code or an additional sequential injection code when the first hour or first injection have not been reported. These requirements simply do not make sense and are artifacts of codes created and defined by physicians for physicians' office use last year. Clinical staff charging at the point of service will not comprehend charging for an additional hour's hydration code when the first hour hydration code has not been charged. In fact, hospitals will have to "un-train" staff because CMS has previously stated that an additional hour code (i.e., 90781) should not be reported without the first hour code (i.e., 90780). The new 2006 CPT codes rely on the concept of "initial service", which means that all other services provided must automatically be reported as "additional" "subsequent", or "concurrent". The fundamental problem hospital charging staff will have with this concept is that it crosses routes of drug administration and will therefore be intuitively difficult to accept.

- Two new CPT codes, 90767 and 90768, for sequential and concurrent infusion respectively, do not follow the hourly structure of the other infusion, hydration, and chemotherapy

infusion codes. The proposed 2006 CPT code narrative, released early by the AMA for review, states: "these codes are reported once per sequential infusion or once per encounter for concurrent infusion". It will be burdensome for hospital staff to apply four different sets of definitions for similar services: initial, additional, sequential, and/or concurrent.

If the descriptions and rules for these CPT codes are implemented in the hospital setting without exception, and as written in the 2006 CPT drug administration section, it will be impossible for hospitals to implement them without heavily involving medical records staff and coders. These staff will be required to code each drug administration claim rather than allowing these services to be charged at the point of care. Furthermore -- and possibly the most difficult issue to accept as a result of the "initial service" concept -- CMS could inadvertently stop paying for services in the future. The PRT does not believe that CMS intends for this to happen, and hopes that this is simply an oversight, but it is one that must be addressed in the final rule. We offer an example below, followed by our recommendation for how to handle it:

A patient is scheduled for a one hour chemotherapy infusion visit. During the course of that visit, an emergency medical condition arises and the patient is taken to the emergency department where hydration is provided, followed by an intravenous injection. The patient is then stabilized but needs to be observed. The physician orders two hours of observation and orders another two hours of hydration to continue. In this example, drug administration services are charged in three different departments. Even if we accept that each department will know what the others provided, and are able to comply with the concept of "initial service", hospitals continue to face a payment reduction given the status indicators that CMS assigned to the descriptions of drug administration services in the 2006 proposed OPPS rule for expected new codes. The table below shows the codes, descriptions, status indicators, APCs, and payment rates generated today -- as well as those expected in 2006 if CMS forces hospitals to abide by the concept of reporting only one "initial" service code.

2005 CPT/HCPCS and Units	SI	Description	2005 APC	2005 Payment Rate		2006 CPT/HCPCS and Units	SI	Description	2006 APC	2006 Proposed Payment Rate
96410 x 1 unit	S	Chemotherapy by infusion, up to one hour	117	168.29		96413 x 1 unit	S	Chemotherapy administration; intravenous infusion technique; up to one hour, single or initial substance/drug.	117	192.14
90780 x 1 unit	T	Infusion by other than chemotherapy, up to one hour	120	111.80		90761 x 3 units	N	Intravenous infusion, hydration; each additional hour, up to eight (8) hours.	N/A	0.00
90781 x 2 units	N	Infusion by other than chemotherapy, each additional hour up to 8	N/A	0		N/A	N		N/A	0
90784 x 1 unit	X	Intravenous IV push injection	359	49.54		90775 x 1 unit	X	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	359	49.33
		TOTAL						TOTAL		

As the table indicates, no payment will be generated for the hydration service started in the emergency department and continued in observation, since hospitals will not be allowed to report another initial service code (chemotherapy is the initial service) . If the 2006 CPT codes are implemented without exceptions and clarification, the nomenclature will result in non-payment for services that hospitals currently are paid for today,

resulting in a significant decrease in payment as shown above which we do not believe is what CMS intended.

If CMS allows hospitals to ignore the concept and word "initial" in each CPT drug administration code, the hospitals would in fact be able to report the following codes to describe the services provided in the above example

2006 CPT/HCPCS and Units	SI	Description	2006 APC	2006 Proposed Payment Rate
96413 x 1 unit	S	Chemotherapy administration; intravenous infusion technique; up to one hour, single or initial substance/drug.	117	192.14
90760 x 1	S	Intravenous infusion, hydration; initial, up to one hour.	120	119.83
90761 x 2	N	Intravenous infusion, hydration; each additional hour, up to eight (8) hours.	N/A	0
90775 x 1 unit	X	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	359	49.33
			TOTAL	

Ignoring the word "initial" would free hospitals to report the payable CPT code 90760, which automatically resolves the non-payment problem illustrated in the first table above and mitigates the financial impact that we again do not believe CMS intends.

If CMS does not allow providers to ignore the word "initial", it will have to find another way to make the additional hours codes payable when used in conjunction with some other "initial" services code.

We do not believe that CMS expects to deny payment in 2006 for the same medically necessary services for which it pays today. CMS can make the codes payable by creating special logic in the OCE, or by requiring hospitals to use modifiers, but both of these solutions are administratively burdensome and inferior to our recommendation that CMS allow providers to ignore the concept and word "initial" in every 2006 CPT drug administration code.

This example clearly illustrates that the codes and descriptions created for the physician setting, now a permanent part of the CPT book, simply cannot work in the hospital setting unless certain exceptions are made and tailored guidance provided. Again, it is not feasible to use codes that were created explicitly for use in one setting in a second setting that is fundamentally different in its structure, staffing, coding/billing/charging, and other operational functions.

The PRT reviewed each 2006 drug administration CPT code in detail and applied the codes to current clinical examples to see if the codes were easy to use, and to identify the key questions raised. We took the time to do this in order to provide CMS with recommendations that the PRT believes are the most reasonable to facilitate an easy implementation of the 2006 drug administration CPT codes starting on January 1, 2006:

- CMS should clearly instruct providers what parts of the CPT text, code descriptions, and narrative hospitals may ignore for reporting under OPPS. At a minimum this means the concept and word "initial" should be ignored for the purposes of reporting drug administration services to CMS. This also extends to the multiple references to "physician supervision" and advanced practice training for administering staff. The PRT expects CMS to follow precedent and instruct providers to disregard this language. CMS has a history of instructing providers to "ignore" certain parts of the CPT definition and/or narrative as it relates to the provision of services in the hospital setting (as described above), and this should not be a problem in 2006.

- The PRT urges CMS to benefit the provider community by working with the AMA to include an introductory, two- to three-page "caveat" section in the CPT book. This section would clearly state which CPT codes, language, guidance, and narrative information hospitals can ignore because the information is irrelevant in this setting. This would be enormously helpful in reassuring hospital staff that they are allowed to disregard (or ignore) the parts of the CPT that are inapplicable. This will likely reduce the questions that CMS receives from hospitals and others about this topic, while increasing the accuracy and completeness of claims data and aiding future rate setting.

- CMS should carefully review the 2006 CPT codes, along with all of the previous transmittals released in relation to OPPS billing for drug administration services, to determine what will carry over for 2006 and what needs to be updated. CMS should not simply re-release the 2005 guidance to physicians for hospitals to use in 2006. The hospital guidance must contain numerous clinical examples including combinations of services, patients that cross departments, and visits that extend overnight or over more than one date of service. The clinical examples should also include documentation time, as that is now a critical piece of the puzzle in determining what codes to report.

- CMS should clearly define all concepts associated with the terms "sequential", "concurrent", "diagnostic", "prophylactic", and "therapeutic".

- CMS should define what solutions are administered as hydration with codes 90760/90761 and confirm that these solutions should be reported under revenue code 258 for IV solutions.

- CMS should clearly define what is meant by the administration of "single or initial substance/drug" (e.g. as in 90774), and provide examples of when it would be inappropriate to report these codes. Today, hospitals report an administration for each medically necessary drug administered. For example, if two drugs are mixed together and administered via one syringe, then only one administration code is reported. If the

same drug is injected more than once in a period of time due to medically necessary reasons, then multiple administrations are charged, even though the same drug is being given. The PRT requests clarification about how this will change with the new 2006 CPT codes.

- CMS must only apply the "initial" service concept on a service-location basis (e.g., each department would charge for what happens in their department based on the applicable codes), as opposed to a visit or claim level basis, even though payment will still be made on a "per visit" basis. This is critical in a hospital setting since patients can receive treatment across multiple departments. The simplest way to achieve this to allow hospitals to simply ignore the "initial" service concept as recommended above.

- Today, CMS only expects to see modifier -59 reported with drug administration services when two or more separate and distinct visits occur on the same date of service. We request that CMS confirm that this is still the only time it expects hospitals to report modifier -59 with respect to drug administration services.

- Our final recommendation is for CMS to carefully review the Excel table that follows below. It includes 2006 CPT drug administration codes for which the PRT makes specific recommendations to CMS.

Table: PRT Recommendations on Problematic 2006 Drug Administration CPT Codes

2005 CPT Code	2006 CPT Code (Preview)	2006 Description (Preview)	PRT Recommendation	Expected Result of Accepting the Recommendation
90780	90760	Intravenous infusion, hydration; initial, up to one hour.	Ignore the word "initial". Clearly define hydration.	Providers can report this for pre-or-post hydration given with chemotherapy or other services (as is allowed today)
90781	90761	Intravenous infusion, hydration; each additional hour, up to eight (8) hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
90780	90765	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to one hour.	Ignore "initial" and explain how this code is different from the hydration code.	Providers consider hydration as a therapeutic service. Therefore, clarifying the difference between the two will minimize confusion.
90781	90766	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour, up to eight (8) hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
n/a	90767	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to one hour.	Define what additional sequential means in terms of the sequence of events or if the sequence does not matter then state that clearly	Minimizes confusion for providers
n/a	90768	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion.	Specify concurrent; does this relate to two or more items being infused at the exact same time per nursing documentation?	Minimizes confusion for providers
90784	90774	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug.	Ignore "initial" and indicate this code should be reported for the first injection provided. Clarify definition of single substance/drug.	Minimizes confusion for providers
90784	90775	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	Clarify definition of new substance/drug; if the same drug is given over time, then would multiple units of 90774 be allowed? If two drugs are mixed and provided through one injection, would two codes be submitted to signifiy the "new drugs"? Implementing the use of this code will be difficult so CMS should provide clear guidance and monitor its use as hospitals are likely to report multiple injections using 90774	Minimizes confusion for providers

PRT Recommendations on Problematic 2006 Drug Administration CPT Codes (continued)

2005 CPT Code	2006 CPT Code (Preview)	2006 Description (Preview)	PRT Recommendation	Expected Result of Accepting the Recommendation
96400	96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic.	Publish and maintain a set of non-hormonal anti-neoplastic drug codes	Takes the guesswork away from hospitals about identifying non-hormonal cancer drugs
96400	96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic.	Publish and maintain a set of hormonal anti-neoplastic drug codes	Takes the guesswork away from hospitals about identifying hormonal cancer drugs
96408	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug.	Ignore "initial". Clarify definition of single substance/drug.	Minimizes confusion for providers
96408	96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug.	Implementing the use of this code may difficult so CMS should provide clear guidance and monitor its use since hospitals are more likely to report multiple units of CPT code 96409.	Minimizes confusion for providers
96410	96413	Chemotherapy administration; intravenous infusion technique; up to one hour, single or initial substance/drug.	Ignore "initial". Clarify definition of single substance/drug.	Minimizes confusion for providers
96412	96415	Chemotherapy administration; intravenous infusion technique; each additional hour, 1 to 8 hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
96412	96417	Chemotherapy administration; intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour.	Clarify sequential	N/A
96423	96423	Chemotherapy administration, intra arterial; infusion technique, each additional hour up to 8 hours.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this.	Minimizes confusion for providers
96425	96425	Chemotherapy administration, intra arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump.	Clarify how to report infusions > 8 hours. If similar to today with an additional line item, then reiterate this. CMS should also define what is meant by "portable" pump.	Minimizes confusion for providers
n/a	96523	Irrigation of implanted venous access device for drug delivery systems	Change the status indicator to "Q" as described in the packaged services section of our comments	Allows payment for this at the low level E/M visit payment when it is the only service provided without forcing providers to report an E/M code

Without the benefit of a grace period, it is essential that CMS think about the implementation effects of this massive coding/billing change. Given that these services are now Charge Master driven, providers need time to either make a process change (e.g., begin to have HIM code these services); or update and test charging and billing systems, create charges for the new codes, update encounter forms, and train staff at the point of service about how to select the new codes to report the services provided.

CMS should not underestimate the magnitude of this change. Nor should CMS discount the enormous amount of time and resources hospitals expend to educate and train staff, update all systems and forms, and monitor the use of new codes to prevent mistakes. Therefore, the PRT urges CMS to implement coding and billing guidance related to the use of the 2006 CPT drug administration codes if not in the Final Rule, then no later than November 30th, 2005. This would provide hospitals with at least 30 days to educate and train their staffs prior to the January 1, 2006 implementation date. This guidance should be comprehensive and timely. It should also include at least one clinical example for each new code and combination of codes that describe expected medical record documentation. Finally, the guidance should be free from contradictions and errors so that CMS is not required to release additional guidance and corrections many months after the codes are in place, as was necessary this year.

10. Blood and blood products

The PRT thanks CMS for continuing to dampen the payment rate fluctuations for blood and blood products. We also appreciate the detailed guidance CMS released earlier this year. We encourage CMS to release guidance on blood and blood products on an annual basis, as hospitals continue to struggle with reporting this correctly. We also urge CMS to explicitly state that hospitals should be charging for blood transfusion/administration the same way in both the inpatient and outpatient settings.

While instructions from CMS speak to reporting blood administration services for OPPS, it is hard to tell what this means for charging inpatients. Medicare retains the cost apportionment rule in the Provider Reimbursement Manual (Publication 15, Part I, Chapter 22, §2203) which states: "so that its charges may be allowable for use in apportioning costs under the program, each facility should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient."

The Provider Reimbursement Manual (Publication 15, Part I, Chapter 22, §2204) concerning Medicare Charges states: "Medicare charges refer to the regular rates for various covered services which are charged to beneficiaries for inpatient or outpatient services. The Medicare charge for a specific service must be the same as the charge made to non-Medicare patients (including Medicaid, CHAMPUS, private, etc.), must be recorded in the respective income accounts of the facility, and must be related to the cost of the service. (See §2202.4.)"

It is not clear what this means for blood administration. For stand-alone ancillary departments, such as an infusion room or the Emergency Department, blood administration services are usually charged the same to both inpatients and outpatients. This may not be the same for nursing units with both inpatients and observation outpatients, however.

Some hospitals do not separately charge blood administration services to inpatients -- the hospital and/or their Fiscal Intermediary consider the service to be included in the room and board rate. Medicare OPPS rules, however, clearly delineate how these services must be coded and charged for outpatients, including observation patients. These patients are often in a bed next to an inpatient on a nursing floor. PRT would like clarification on whether blood administration services performed on nursing units should be charged to inpatients as well as to outpatients. According to the rules above, blood administration services should be separately charged in the same manner to patients seen both in the inpatient and outpatient setting.

11. Observation Services

The PRT commends CMS and the APC Advisory Panel's Observation Subcommittee for the continued and thoughtful work they have performed in studying the administrative issues related to coding and billing and the payment criteria for the separately payable observation APC, and for taking additional steps to propose a set of changes that will result in further streamlining the reporting of these services.

The PRT's understanding of the current proposal is that providers would use a single G-code to report medically necessary observation on an hourly basis, regardless of the diagnosis or the actual hours in observation. This means, for instance, that providers could report two hours of observation time provided to a patient admitted to observation from the Emergency Department with abdominal pain using the newly proposed GXXXX. The UB-92 would show one line item with GXXXX, the date of service, and two (2) in the units of service field that correspond with two hours in observation. CMS' claims processing system and/or the OCE editor would determine that the reporting of GXXXX in this situation does not meet criteria for separate payment of APC 0339, since one of the required diagnosis code for the separately payable observation was not present on the claim and since less than eight hours of observation were provided per the units reported on the line item of GXXXX. The PRT fully supports and appreciates CMS' use of programming logic to determine whether separate payment is warranted rather than requiring providers to make that determination as a part of their coding and billing process.

Additionally, CMS has proposed HCPCS code GYYYY to replace existing HCPCS codes G0263 and G0264 for reporting patients directly admitted to observation. The PRT also supports this change, since the burden of determining which G-code to report will be removed and will no longer be dependent on whether or not certain criteria are met. We understand and agree that CMS' claims processing logic will determine whether payment for GYYYY is warranted and this will be based on whether criteria are present to trigger payment for GXXXX. In other words, if payment is not made for GXXXX, then CMS will make payment through its claims processing logic for GYYYY at the low-level clinic visit APC 0600.

The PRT whole-heartedly supports this logic and believes this simplification in how providers report separately payable observation will result in providers reporting all observation services more completely and accurately. This, in turn, will provide CMS with the data it needs to determine if additional conditions warrant separate payment for observation in the future.

The only additional change the PRT requests for 2006 is the addition of specific diagnoses for COPD that parallel the current "well-defined set of hospital services" for asthma. The PRT believes that CMS should expand the diagnosis codes that meet reimbursement requirement for the separately payable observation APC related to asthma to include all of the asthma diagnoses, including chronic obstructive lung disease codes as well.

Currently, the following diagnosis codes will support separate payment for observation services for asthma:

493.01 - Extrinsic asthma with status asthmaticus
493.02 - Extrinsic asthma with acute exacerbation
493.11 - Intrinsic asthma with status asthmaticus
493.12 - Intrinsic asthma with acute exacerbation
493.21 - Chr obstructive asthma with status asthmaticus
493.22 - Chr obstructive asthma with acute exacerbation
493.91 - Asthma, unspecified with status asthmaticus
493.92 - Asthma, unspecified with acute exacerbation

CMS included some patients with chronic obstructive pulmonary disease (COPD) when it included diagnoses 493.21 and 493.22, but excluded others. The assignment of the asthma and COPD codes can vary widely depending on the specificity of the physician when listing the final diagnoses. Physicians are frequently non-specific in stating a diagnosis, which can lead to non-payment even when the level of care and services provided to the patient remain the same. In addition, a patient may have combinations of disorders. A patient with asthma may have elements of bronchitis, and a patient with bronchitis may have elements of asthma.

Respiratory practitioners will confirm that, in a hospital setting, the care of the patient with asthma, bronchitis, and COPD is very similar as far as the diagnostics performed, the medications ordered, and the clinical care provided. ABG, SaO2, chest x-ray, nutritional assessments, and sputum and blood cultures are frequently performed as diagnostic tests for each. Medications may be delivered via nebulizer, inhalers, oral, or intravenous routes and include bronchodilators, corticosteroids, and possibly antibiotics. Clinical assessments, care planning, and patient education are also similar.

Therefore, the PRT requests the following diagnosis codes be added to the asthma codes currently covered as payable diagnoses for the separately payable observation APC under OPPS, and the category be expanded to cover both patients with asthma as well as COPD:

466.0 - Acute bronchitis
466.11 - Acute bronchiolitis due to RSV
466.19 - Acute bronchiolitis due to oth infcts organsm
491.21 - Chr obstructv bronchitis, w acute exacerbation
491.22 - Chr obstructive bronchitis, w acute bronchitis
496 -- Chr obstructive pulmonary disease

Once again, the PRT wishes to thank CMS and the APC Advisory Panel for listening to the operational burdens that providers face and for taking the appropriate steps to reduce them. Finally, we urge CMS to work diligently to ensure that the final rules for the separately payable observation APC, as published in the *Federal Register*, are promptly imported into the CMS Online Manual via appropriate "Changes in Manual Instructions". Last year, as CMS is aware, several contractors continued to require diagnostic testing in their local coverage determinations for the separately payable observation APC simply because the language from the final rule and subsequent transmittals had not yet been incorporated into 100-4, §290.4.2. We urge CMS to make sure that FIs implement the finalized changes correctly and in a timely fashion.

12. Inpatient-Only List

The PRT appreciates CMS' proposal to remove 25 procedure codes from the Inpatient-only List. We continue to strongly support the APC Advisory Panel's recommendation that CMS eliminate the list altogether, however. Rather than using an Inpatient-only List to control provider behavior, the PRT suggests that CMS rely on its Peer Review Organizations (PROs) or Quality Integrity Organizations (QIOs) to examine any questionable cases. These organizations are best equipped to handle issues related to care provided in inappropriate sites of service. We have provided some of the reasons that the PRT believes the list should be eliminated below:

The decision to admit a patient is a medical decision based on a physician's assessment and requiring a specific order to admit to an inpatient status. In the past, CMS has focused on "medically necessary" services, and hospitals have worked diligently to educate physicians regarding inpatient admission criteria as well as providing and documenting medically necessary services. The Inpatient-only List inhibits providers from making medically necessary decisions about which patients require hospital admission. Hospitals are, in this manner, put in the difficult position of either asking physicians to admit patients who may appropriately be cared for in the outpatient setting, or providing expensive "Inpatient-only" procedures to patients in the outpatient setting and without being reimbursed.

In addition, the Inpatient-only List is very difficult to implement, since physicians resent being told what can and cannot be provided for patients when they believe the services are medically necessary and can be provided safely in an outpatient setting. This issue is beyond preventive measures that a hospital can reasonably take as it is ultimately the physician's order and intent that dictates the admit status.

Sometimes patients are scheduled for procedures that are not on the Inpatient-only List and can be performed safely and effectively in the outpatient setting; therefore, the physician makes no plans to admit the patient. During some procedures, however, a surgeon might perform a second procedure that *is* on the Inpatient-only List, or which modifies the original procedure so that it becomes one on the Inpatient-only List. The surgeon either is unaware that the second procedures is on the Inpatient-only List, or has to provide the service because to do otherwise would be poor medical practice.

In the above circumstance, in order to be paid, the hospital must find a way to immediately identify the second procedure as being on the Inpatient-only List, so that the physician may be

approached about admitting the patient to inpatient care. In many cases this is unrealistic. When it is feasible, but the physician does not agree, the hospital has no recourse except to lose the reimbursement if it is to act in the best interest of the patient. In most hospitals, identification that the second procedure is on the Inpatient-only List does not occur until the record reaches the coding department following discharge. Once a patient is discharged, the admit status cannot be changed to an inpatient admission status. The hospital is forced to bill the claim as an outpatient knowing there will be no reimbursement.
In the event that CMS chooses not to eliminate the Inpatient-only List, the PRT requests that CMS post the Inpatient-only List on the physicians' web-page of the CMS web-site and provide background detail on the Inpatient-only List. We also request that CMS discuss this issue on the Physician Open Door Forum, in the MPFS proposed and final rules, We also request that CMS require carriers to post the Inpatient-Only list in their educational materials. In this fashion, CMS will educate physicians and facilitate hospitals' education efforts with physicians.

The PRT also requests CMS to review Category III CPT Codes as soon as they are released to determine if they belong on the Inpatient-only List. We urge CMS to provide its rationale for new codes and services added to the Inpatient-only List in a proposed rule so that providers can submit comments. The PRT also asks that CMS clarify in the final rule that just because services are NOT on the Inpatient-only List does not mean that they can only be provided in the outpatient setting. In other words, CMS should make clear that it has NOT created an "outpatient-only list". This will help providers to communicate clearly with other payers who often use a code's absence from the CMS' Inpatient-only List to identify services that can only be provided in the outpatient setting. We know this is not the intent, which is why we kindly request CMS to state that fact in the final 2006 OPPS rule.

Finally, the PRT continues to urge CMS to consider removing the following codes from the Inpatient-only List as they can -- and often are -- provided safely in the outpatient setting:

- *CPT code 58260 (vaginal hysterectomy not including tubes and or ovary)*
- *CPT code 63075 (Diskectomy)*
- *CPT 44603 (Suture, small intestine), 44602 (Suture, small intestine) and 44604 (Suture, large intestine)*
- *CPT 49000 (Exploration of abdomen)*
- *CPT 58940 (Oophorectomy, partial or total, unilateral or bilateral)*

The PRT again asks CMS to go beyond using the 60% threshold in determining what procedures are acceptable to be provided in the outpatient setting. So long as payment is tied to the procedure being performed in the inpatient setting, providers will be discouraged from finding new and safe ways to perform the procedures on an outpatient basis — despite advances in new technologies. In addition, it may be appropriate for the same procedure code to sometimes be performed as an inpatient procedure, and sometimes as an outpatient procedure, based on medical necessity. This should be based on the physician's judgment and individual patient situation rather than on the Inpatient-only List.

Please note that some Fiscal Intermediaries are now instructing hospitals to move the Inpatient-Only CPT to the non-covered column of the UB92 claim and re-submit the claim to allow payment for the other services under OPPS. The PRT is concerned that, under this system, some hospitals receive payment when other hospitals do not. The PRT asks CMS to issue instructions to ensure that every FI handles such situations in the same way as it is not being implemented consistently by all FIs.
Finally, the PRT requests that CMS review both hospital and physician utilization rates for these procedures, since physicians do not have the same restrictions on where procedures must be provided as hospitals do. This is just one of several examples of policy and/or payment differentials between hospitals and physicians noted by the PRT in our comments.

13. Status Indicators

The PRT supports the creation of status indicator "Q" to indicate packaged services that are subject to separate payment under OPPS payment criteria. It is not clear, however, whether this status indicator is going to be assigned to any CPT/HCPCS codes starting January 1, 2006. The PRT believes that this status indicator should be assigned to several codes representing services which can be, or are, the only services provided to patients on a given date of service. We described several of these services in detail in the section on packaged services and encourage CMS to refer to that section for our rationale for assigning the following codes status indicator "Q" in 2006:

- Non-selective Debridement CPT code 97602
- Collect Blood Venous Device 36540
- Withdrawal of Arterial Blood 36600
- Injection Procedure for Sentinel Node ID 38792
- Irrigation of implanted venous access device for drug delivery systems (expected 2006 CPT code 96523)

If we understand the purpose of Status Indicator "Q" correctly, and the above codes were to be assigned a status indicator "Q" for 2006, then separate payment would be made for each of the codes above when the services provided are the only OPPS payable service on a date of service. Payment would be made through APC 0600. If other OPPS payable services are provided, then the OCE would not make separate payment for the above codes and would, instead, treat the service as if it were still a status indicator "N" service. If our understanding is incorrect, the PRT would appreciate CMS clarifying the payment implications associated with services assigned Status Indicator "Q".

14. Payment Reduction of Diagnostic Imaging Services

The PRT understands that CMS has proposed to apply a 50% discount when two or more diagnostic imaging procedures from the same family of codes are provided during one session because CMS assumes the provider gains economies to scale. The PRT agrees with CMS that some economies to scale are generated when similar radiology procedures are performed during the same session, but we disagree with CMS' proposal to reduce the payment rate of the second and subsequent APCs by 50%.

Such a reduction ignores the fact that some of the economies to scale are already reflected in the cost-to-charge ratio used by CMS to arrive at the median cost data. Furthermore, the PRT notes that CMS does not currently pay hospitals for procedures that take longer as a result of problems with the patient's clinical condition. If CMS implements a reduction in payments, a modifier (such as modifier –22) should also be established to indicate increased costs, when incurred. The PRT recommends the additional payment be made at the same percentage as the reduction in payment being considered. CMS should instruct hospitals to apply the increased cost modifier to any affected radiology procedure; and provide specific guidelines as to what events constitute increased cost, as well as documentation needed to support the modifier.

In addition, CMS states in the proposed rule that private payers are already discounting in the same manner as proposed by CMS. In fact, none of the PRT's 18 members has a single payer that applies such a reduction in payment; we caution CMS against drawing assumptions about what private payers are doing and the extent to which they follow Medicare's lead.

The PRT also has questions about the family of codes CMS proposes. For example, the PRT disagrees with CMS' proposal to discount CPT code 76830 (transvaginal ultrasound, non-ob) when provided during the same "session" as CPT code 76700 (echo exam of abdomen). Routinely, when a patient has a transvaginal ultrasound following ultrasound of the abdomen, the patient must leave the room to empty her bladder, the room must be set up again for this separate procedure, and a different probe installed. In this situation, we do not believe economies of scale exist that would warrant a 50% payment reduction for the second procedure. Therefore, if CMS chooses to move forward with its proposal, the PRT urges removal of the transvaginal procedure represented by CPT code 76830 from the list of services included in Family 1.

A second example is provided by CT Abdomen and CT Angio Abdomen. To the best of our knowledge, these services are never provided during the same session, yet CMS has assigned them to the same family of codes. Again, if CMS proceeds with its proposal we recommend that it only assign procedures to the same family if the procedures are commonly performed during the same session, and exclude those that are rarely performed in the same session.

The PRT is also not clear on what CMS means by separate "session". If CMS proceeds with this proposal, the term "session" must be explicitly defined so that providers know when they can and should use modifier -59 to signify that multiple diagnostic radiology procedures were performed on the same date of service, but NOT during the same session. CMS will need to define "session" in a way that distinguishes it from other terms, such as "encounter" or "visit", so that hospitals will use modifier -59 appropriately in order to be paid 100% for both or all of the subsequent procedures provided (if done during different sessions).

The PRT urges CMS to delay implementation of this proposal until it has fully studied and analyzed both provider claims and cost report data to determine if, in fact, a further reduction in payment is warranted or if economies to scale are already being captured through the departmental cost-to-charge ratio. In addition, the PRT encourages CMS to consider working with the AMA to simply create new CPT codes that describe commonly combined procedures so that data can be more systematically collected and payment rates naturally be set from provider charges for these combined procedures as reported through the claims data. Furthermore, this

would ensure that the ordering physician intended for both exams to be performed and a single radiologist report would be produced that addresses the combined exams.

15. **Interrupted Procedures (modifiers -52, -73, & -74)**

Since implementation of the OPPS in 2000, CMS has required hospitals to report modifiers –52, -73, -74 to indicate procedures that were terminated before their completion. Over the years providers have struggled to understand how to use these modifiers, in particular whether conscious sedation is considered anesthesia by CMS or not. Clarification on this issue was released earlier this year, and while helpful CMS needs to continue addressing other questions providers have about the use of these modifiers.

For CY 2006, CMS is proposing to decrease payment for services when modifiers -52 and -74 are reported. The PRT disagrees with this proposal and explains why below.

Modifier –52

The PRT requests that CMS continue making full payment (100% of the APC payment) for services reported with modifier -52. The PRT believes that the same level of resources is consumed whether the service is provided in full or discontinued part way through the procedure. Clearly, procedures that are cancelled or discontinued at the very start due to patient's being nervous or worried should not be charged. The procedures under discussion are already underway, which is why the PRT believes that the same amount of resources (and, in many cases, even more resources) are consumed than would be required to complete the normal procedure. This is true both for modifier -52, and even more so for modifiers -73 and –74, which are discussed below.

An example is CPT 74485 (dilation of nephrostomy, ureters or urethra), in which a patient presents for dilation of both ureters due to bilateral strictures, and multiple dilating balloons are used. In a hypothetical case, the dilating balloon is passed into the stricture in the right ureter, the balloon is inflated, and the stricture is opened. The balloon is then moved to the left ureter. The balloon, however, will not cross the stricture, and a smaller balloon must be selected. In this case, several balloons of different sizes are used in an attempt to dilate the stricture. The patient is likely to complain of discomfort which may result in the physician terminating the procedure. Because this CPT code includes "ureters", the scenario described would be correctly reported with modifier –52. The resources and supplies required for the failed procedure are actually higher than for an uncomplicated, completed procedure. If the attempt to dilate the left ureter had been successful, fewer supplies and resources would have been used, and the procedure reimbursed at 100 percent. However, because the left stricture required multiple attempts to dilate (the stricture), the hospital incurred the cost for more balloons and consumed more procedure time.

The PRT does not believe that circumstances such as "equipment failure" are an acceptable reason to apply modifier -52. Several attempts and time may be exhausted to complete a procedure that is not successful -- such as an attempt to re-position a patient to complete a procedure, or several attempts to establish a picc-line insertion. In both scenarios, resources and

supplies are utilized. All of the same resources have been exhausted even though the procedure is ultimately reduced. In some cases, more resources are utilized due to the patient's size or difficult anatomy, or because several attempts are made that increase time and overhead. The PRT believes it is inappropriate for CMS to reduce payment for procedures reported with modifier -52 from 100% to 50% and urges CMS to better understand provider operations and resource consumption before implementing such a decision. Given the relatively low frequency with which this modifier appears in the claims data, the PRT believes providers are either still very confused about when to report these modifiers (and are simply not reporting the services at all), or they are just not canceling or discontinuing as many procedures as some might think. Without further review, providers who truly must discontinue procedures and who incur the expenses will face unwarranted financial impact .

Modifier -73

The PRT concurs with the APC Advisory Panel and recommends that CMS make full APC payment for services reported with modifier -73 because of significant use of hospital resources in preparing the patient for the treatment or operating room. The PRT further requests that CMS remove the language "taken into the treatment room," from the current policy because, in many cases, it prevents the legitimate application of modifier -73.

Patients are often prepared for surgery in various settings of hospital based on space availability, including pre-operative and holding areas. Preparation in these areas incurs the same costs as if the preparation occurred in the treatment or operating room. The current definition of modifier -73 requires the surgery to be cancelled in the room where the surgery is to occur. Although the patient may not go to the treatment room, sterile surgical supplies have been opened and other resources (such as staff time and scheduling) consumed; providers cannot recoup these costs because modifier -73 is not allowed.

For example, a patient is registered, a medical record is created, and an initial assessment completed. The patient changes into a hospital gown and is taken to a bed or other space in a pre-treatment room or holding area. The nursing staff takes the patient's vitals and provides education in preparation for the procedure. An IV may be initiated at this time to start medications; many physicians order pre-operative medications to be given while the patient is in the holding room. Some of these medications have a sedative property, but are not considered to be anesthesia. At this point, the procedure room has been prepared for the patient, and sterile supplies opened, in order to expedite beginning the procedure as soon as the patient is taken into the procedure room and positioned on the table. Hospitals manage their resources by ensuring that procedure rooms are ready and supplies available for procedures before the patient enters the room. (Research indicates that patients become anxious and worried if there is a delay in beginning the procedure when they enter the procedure room. In addition, waiting to set-up and open supplies until after the patient enters the room causes cumulative delays in the surgical suite.) In this hypothetical case, the patient experiences elevated blood pressure during the final pre-procedure processing while the patient is still in the holding area, and the physician decides that the procedure must be discontinued. Clinical care must still be provided to the patient after the point of discontinuation until he or she is stable and ready for discharge

In this case, the hospital has expended a large number of resources in caring for this patient pre-operatively, but the current reimbursement to the facility is "$0.00". The hospital cannot bill the procedure with modifier -73 since the patient did not enter the procedure/operating room. The reality is that in many cases of cancelled procedures even more hospital resources are expended than are involved in a normal procedure. Some providers bill nothing in the above example since the patient was not taken into the procedure room, while others are reporting an E/M visit code to recoup some of their costs.

Therefore, the PRT requests that CMS allow providers to use modifier -73 for cancellation of procedures for patients in a holding room or a pre-operative suite when the patient is clinically prepared for surgery and resources have been utilized. When a procedure is cancelled prior to clinical preparation of the patient, there is little resource utilization and modifier -73 would be inappropriate and providers are aware of this, but CMS could reiterate this point in the final guidance. If CMS does not change the description of modifier -73 to allow hospitals to report it with procedures cancelled prior to the patient entering the treatment room, then it should clearly tell providers that they are allowed to report an appropriate E/M visit code to recoup some of the costs incurred.

Modifier –74

The PRT concurs with the APC Advisory Panel's recommendation that 100% of the APC payment be made for services reported with modifier -74. This is CMS' current policy and the PRT believes it should not change in any way, as providers typically face full and often increased costs when modifier -74 is used. CMS suggests that the same costs are not incurred when a procedure is canceled and suggests that providers are able to report additional services provided and receive payment for them. The PRT strongly disagrees with these statements and believes CMS should rethink its position. In many circumstances, a procedure is cancelled due to the patient's anatomy or a complication of the patient's condition. This may extend the procedure time beyond the normal period. A hospital is not allowed to receive additional payment for the prolonged procedure time. Physicians (professional services) recoup unusual procedure services with modifier –22, but hospitals do not have the luxury of doing so.

The PRT does not believe that resources are necessarily reduced when a procedure is cancelled. For example, an endoscope procedure may only be partially completed because the surgeon encounters a mass before the scope can be advanced to the furthest point (as described by the CPT code). Several attempts and time may be exhausted to maneuver around the mass and evaluate the extent of the disease. In many cases, additional costs are consumed in an attempt to complete the procedure. Full payment should be allowed for the completion of the procedure, since the full use of resources was exhausted.

Hospitals do their best to manage their resources by screening patients for possible complications that may cause the procedure's cancellation. Because each patient is unique, however, it would be impossible to anticipate and avoid all complications. Complications include -- but are not limited to -- excessive bleeding, hypotension, hypertension, tachycardia, bradycardia, and reactions to anesthesia drugs or gases. The physician and/or anesthesiologist attempt to manage complication(s) and complete the procedure, but there are times when it is in the patient's best

interest to discontinue the procedure. The decision point for discontinuation will vary based on the individual situation. If a patient has a reaction to an anesthesia drug or gas, the procedure may be discontinued before an incision is made, however, significant resources have already been expended.

Once anesthesia is initiated, the hospital has every expectation that a procedure will be completed and, therefore, supplies are opened and ready for use during the procedure. (In fact, surgery departments report that expensive implants are not usually opened until the physician is sure which implant will be used; at that point, the patient is already in the surgery/treatment room.) Once the usual supplies are opened and the patient has entered the room, the supplies cannot be used for a different case. To wait to open each item until the physician is ready to use it would increase procedure time, require additional staff in the procedure room to anticipate the physician's needs, and could cause the patient to be anesthetized longer than necessary. Once anesthesia is administered, there is no turning back in terms of hospital resources being expended. The post-procedure care of the patient does not change: anesthesia must be reversed, the patient must be recovered, and post-operative pain control managed. In fact, complications that cause a procedure to be interrupted often require longer recovery times than would be necessary for a completed procedure, which results in increased cost to the hospital which is not covered.

Supplies and recovery time are all packaged services and the costs are covered by the APC for the procedure; therefore, reducing the reimbursement when modifier -74 is appended will negatively impact hospitals. Many hospitals bill for surgical procedures based on the time the patient is actually in the surgical suite or procedure room. These facilities are already reporting any decrease in procedure time which will reflect the decreased cost through the claims and cost data used by CMS to set future APC payment rates.

The PRT also disagrees with CMS's assertion that additional services are separately payable under OPPS and therefore the hospital's costs need not be paid through the APC payment for the planned procedure. Initiation of other APCs that are currently separately payable will not recoup costs for the cancelled procedure. Most of the services required to stabilize a patient are the same charges inherent to the procedure, such as anesthesia, recovery, staff, related supplies, and drugs (which are generally packaged).

APC payments made for additional services are intended to cover the costs for providing those services, and cannot be counted on to cross-subsidize the loss taken on the payment rate for the cancelled procedure. Services provided that generate separate APC payment would simply cover the cost of providing those APCs. Moreover, certain services that are provided as part of a surgical procedure (such as injections and infusions) are inherent to the procedure and not separately reportable. This means that, if the procedure is cancelled, providers would have to begin thinking about charging for those services, which is counter-intuitive to their training NOT to report these services because they are a part of the procedure. In short, the PRT disagrees with the contention that separate APCs billed would cover the costs associated with the cancelled procedure.

Finally, CMS should recognize that the majority of the upfront costs in providing a service occur in the procedure's first hour. When the physician reaches a point at which a procedure cannot be completed, the resources have already been expended. Again, CMS' own data shows that the use of modifier -74 is infrequent. Therefore, the PRT urges CMS to continue making 100% APC payment for services that are discontinued in order to provide hospitals adequate reimbursement to cover the costs they have incurred.

Conclusion

The Provider Roundtable would sincerely like to thank CMS and its staff for reviewing and considering our comments. Although we are still a relatively new group, the PRT members are very encouraged by the policy-making process and appreciate how our input can have an impact on future year's rules and policies. We are very grateful to CMS for considering our comments in past years as well as again this year. We hope the operational issues we have outlined will be helpful to CMS in considering future system changes. If you have any questions or require additional information, please contact our spokesperson Valerie Rinkle, listed below.

Comments were submitted electronically by Valerie Rinkle, MPA, Asante Health System. A full list of the provider roundtable members is included below in **Appendix A**.

Sincerely yours,

Members of the Provider Roundtable

Appendix A: Current Members of the Provider Roundtable

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Our Lady of Lourdes Regional Medical Center
Lafayette, LA

Kathi L Austin, CPC, CPC-H, CCP
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Sisters of Mercy Health System
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Barbara Bunge, RHIA, CCS, CCS-P
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Kathy Dorale, RHIA, CCS, CCS-P
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Louisville, KY

Submitter : Michael Rodgers **Date:** 09/13/2005

Organization : Catholic Health Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-370-Attach-1.DOC

September 9, 2005

Honorable Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1501-P

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

Dear Dr. McClellan:

The Catholic Health Association of the United States (CHA) is pleased to submit the following comments on the notice of proposed rulemaking (NPRM), Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (*Federal Register*, Vol. 70, No. 141, pages 42673-43011) published July 25, 2005.

1. Inpatient Procedures

CHA urges CMS to eliminate the inpatient procedure list primarily because the list is not binding on physicians.

The list was created to identify procedures that are typically provided only in an inpatient setting and, therefore, would not be paid by Medicare under the Hospital outpatient prospective payment system (OPPS). There are numerous problems created by the inpatient procedure list as has been documented in past comments. The biggest continuing problem is that such a list is not binding on physicians. Since the physician only receives payment when a procedure on the inpatient list is performed on an outpatient basis, there is no incentive for the physician to be concerned whether Medicare will pay the hospital for the procedure. This fact underscores the fact that it is the physician, not the hospital, who determines whether a procedure will be performed in the outpatient or inpatient setting.

In the past, CMS has responded to such comments by saying that "[it] believes that appropriate education of physicians and other hospital staff by CMS, hospitals and organizations representing hospitals is the best way to minimize any existing confusion." From our perspective, having hospitals or their representative organizations try to educate physicians on the appropriate use of the inpatient procedure list tends to be fruitless. When it comes to economic issues, physicians, quite understandably, pay little attention

to how hospitals are paid. In addition, the CMS provider education staff appears to have made little headway on this matter as well.

This issue was initially raised when CMS first published the inpatient procedure list in 2000, and the situation has not improved. In fact, it has worsened, as physicians are now much more focused on increasing outpatient procedure volume.

2. APC Relative Weights

CHA continues to object to the year-to-year volatility of the APC weights and urges CMS to take appropriate steps to ensure stability in APC weights. One approach is to adjust medians derived from claims data to limit the amount of change that occurs from year-to-year. CHA recommends a stabilization policy which adjusts the medians from claims data to ensure that no APC medians fall more than 5 percent above or below medians used for payment in CY 2005.

The CY 2006 proposed rule shows significant swings in the APC weights. For 65 APCs, the 2006 proposed weights would decrease by 10 percent or more; for 11 of these, the reduction is greater than 20 percent. In total, weights would be lower for 235 APCs. On the other hand, weights increase for 176 APCs, going up 10 percent or more for 46 of them. In fact, 21 APCs would rise by 30 percent or more. This high level of unpredictability in APC weight changes is not acceptable and should be moderated by CMS.

3. Device-Dependent APCs

CHA strongly recommends that CMS, for CY 2006, continue the CY 2005 policy of limiting device dependent APC payment losses to no more than 5 percent of the median costs determined for the prior accounting year. Specifically, continuation of this policy would ensure hospitals are paid the higher of either the CY 2006 unadjusted median, or 95 percent of the adjusted median determined for CY 2005.

In CY 2005 CMS adopted the above policy to begin the transition to the use of pure claims data for all APC services in order to ensure the appropriate relativity of the median costs for all payable OPPS services. While CHA understands and appreciates this goal, we believe such a transition must be deliberate because too much is at stake for unnecessary haste. The policy must do a better job of balancing the desirability of the goal and the continued availability of critical and essential outpatient services for Medicare beneficiaries.

A cut of support from 95 percent to 85 percent of the CY 2005 median could well tip the scale against the continued offering of such services, a most undesirable effect. Our rationale is based on the fact that, since HCPCS codes were not required in 2004, CMS still does not have adequate data to be used in calculating the payment rates for device dependent APCs. Specifically, CMS has used claims data both with and without C-codes

to generate the APC payment rates for device dependent APCs. At a minimum, CHA urges CMS to only use correctly coded single procedure claims.

4. Outlier Payments

CHA urges CMS to provide a technically supportable rationale for reducing the projected target for aggregate outlier payment from 2.0 percent to 1.0 percent of aggregate total payments under the OPPS.

While CMS proposed to reduce the projected target for aggregate outlier payments from the original 2.0 percent to 1.0 percent, it did not provide any analytical support for this policy decision. Instead, CMS cited a number of reasons for its decision, but provided no supporting analytical rationale.

In the proposed rule, one reason cited by CMS for the proposed reduction was that "the distribution of outlier payments benefits some hospital groups more than others." This is true for the inpatient PPS as well, but in this case CMS has not proposed minimizing the outlier pool consistent with the statute. The above hardly seems sufficient reason to reduce the pool – as this observation could also be viewed as signaling a continuing protection need which benefits only certain types of facilities.

In closing, CHA appreciates opportunity to provide CMS with our comments on the proposed hospital outpatient PPS rule for CY 2006 and hopes our recommendations are helpful in developing the final rule.

Sincerely,

Michael Rodgers

Interim President and CEO

Submitter : Mr. Tom Silver

Date: 09/13/2005

Organization : Mr. Tom Silver

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

A 2% "handling cost" above the ASP is inadequate to cover the handling costs of drugs.
The June 30, 2005 report from Medicare Payment Advisory Commission (MedPAC) noted that handling costs "made up 26 to 28 percent of pharmacy departments' direct costs."
Small hospitals, particularly, may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous.
I support the Proposal being made by the Assoc. of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the acquisition cost.
CMS MUST collect hospital charge data for overhead costs for two years to determine if even the 8% rate is adequate and consider new reimbursement rates for these costs for payment in 2008.

Submitter : Ms. Kimberli Davenport **Date:** 09/13/2005

Organization : Tucker Maxon Oral School

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

First I'd like to acknowledge CMS' responsiveness in working with cochlear implant providers and manufacturers to ensure adequate Medicare payment rates. I am greatly concerned about the proposed 14% decrease in reimbursement, as this would make access to this service even more difficult than it already is. A large body of evidence based literature documenting the cost effectiveness of cochlear implantation is accepted by both the medical profession and insurers. I work with children in a private oral school, over 70% of whom are cochlear implant users. Most of these children are near, at, or above grade level in many areas due to their ability to hear with a cochlear implant. My clinic is a satellite programming center for Oregon Health Science University, the second largest implant program on the West Coast. People already have to travel great distances for surgery and programming. The proposed level of reimbursement would reduce the number of centers offering implantation, hampering access for implants and follow up care for Medicare benificiaries and others because of a shortage of implant audiologists and surgeons. Please substitute accurate external device cost data as determined by the Lewin Group Study and recalculate the relative wight of APC 0259. Alternatively, please set the 2006 OPPS payment no lower than 100% of the 2005 payment rate plus the inflation and other update factors applied to all APC's. Thank you for your recognition of the impact of payment rates on access to care and for your consideration of my comments.

Submitter : ROBERT AND PHYILIS CLEMENT **Date: 09/13/2005**

Organization : ROBERT AND PHYILIS CLEMENT

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

753 Hurlbut Ave.
Sebastopol, CA 95472
September 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-P
PO Box 8017
Baltimore, MD 21244-8017

Re: GPCIs

We are Medicare beneficiaries who receive medical care from a physician in Sonoma County, California. We understand that Medicare is proposing to create a new payment locality for Sonoma County. This is an increasingly expensive place to live and work. In the new locality, the Medicare reimbursement rate would be more closely matched to actual practice expenses than it is now.

The new locality would help Sonoma County physicians improve the quantity and quality of care which they deliver to us and other Medicare beneficiaries and upon which we depend so vitally. The locality change would also benefit efforts to recruit and retain physicians in the county, which has a large Medicare population. Our county needs more physicians and they must be satisfied to live and work here.

We fully support your proposal to change Sonoma County?s payment locality, and we appreciate the opportunity to comment on this important issue.

Sincerely,

Robert C. and Phyllis V. Clement

Submitter : Mrs. Jean Baumeister

Date: 09/13/2005

Organization : ENT Nebraska

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment
File Code:CMS-1501-P
Issue Identifier: Device-dependent APCs

CMS-1501-P-375-Attach-1.TXT

Attention: CMS-1501-P

CATHOLIC HEALTH INITIATIVES
Saint Elizabeth Physician
Network
Alan J. Nissen, FACS
Thomas J. Tegt, MD
ENT NEBRASKA
September 13, 2005

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8018

To Whom It May Concern:

I am concerned with your proposed 14% decrease in the baseline payment of cochlear implantation. I believe this decrease will have a significant effect on the availability of cochlear implants for the profoundly hearing impaired individuals that have Medicare and Medicaid. We are the only medical practice in Lincoln, Nebraska that provides cochlear implants. We draw from a large area west and south of us because the nature of this specialty it is not widely available. In our practice the only people that have received implants are Medicare or Medicaid recipients. If we discontinue our cochlear implant program these types of patients will probably not receive this service. For many it is not possible to drive to a further site.

I believe that the quality of life changes dramatically for those that are implanted. Without hearing you are cut off from much of the "world". You are unable to communicate with your family because writing notes takes too long and family members are not always willing to write every conversation down. Grandchildren are often the joy in elderly people's lives. Without hearing those little voices, they are missing much of those little people's lives. I programmed a processor for a 40-year-old gentleman on Medicaid who had not heard well for years. Giving him sound back was for me, as well as for himself and his family, indescribable. Imagine hearing birds singing, your mother talking and the possibility of obtaining a job for the first time all because you can now hear.

With this decrease I believe we will be forced to discontinue our implant program. As I stated above this will keep some individuals from hearing. It is well documented that the cost effectiveness of cochlear implantation is another reason why taking this option away from Medicare/Medicaid recipients is not in anyone's best interest.

I ask that the Center for Medicare and Medicaid Services substitute accurate external device cost data as determined by the Lewin Group study and recalculate the relative weight of APC 0259. I also request

that the CMS set the 2006 OPPS payment no lower than 100% of the current rate plus the rate of inflation.

Thank you for your attention in this matter.

Sincerely,

Jean M. Baumeister, M.S., CCC-A
Clinical Audiologist
A spirit of innovation, a legacy of care.
575 S. 70th Street, Suite 440
Lincoln, NE 68510
Phone 402-484-5500 Fax 402-484-5501

Submitter : Ms. LuAnn Weis

Organization : St. Joseph's Hospital Medical Center

Date: 09/13/2005

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1501-P-376-Attach-1.TXT

CMS-1501-P

2005/9/13
St. Joseph\rquote s Hospital Medical Center Provider # 310019
2006 Proposed OPPS Rule

CMS should release clear guidance on the use of the new drug administration CPT codes as soon as possible . Also, will the new codes apply to both dialysis composite and non-composite drugs? CMS should release clear and concise guidance on the reporting of the drug handling cost. Administrative costs need to be defined vs. handling costs. The overhead cost associated with the administration of each separately payable drug, and biological used should be clearly defined. CMS will update the ASP of drugs quarterly, so payment rate will change quarterly; how will this information be communicated to providers on a timely basis?

Since there is no average sale price for radio-pharmaceuticals, providers will bill hospital charges, and will be reimbursed costs, using the hospital specific costs to charge ratio applied to either reasonable charges or hospital specific charges. Please provide more specifics on this reimbursement methodology. Regarding Diagnostic Imaging Procedure families: what happens if one member of the family is performed at a facility, and another member of the family is performed at another location on the same day; how will that be reimbursed?

Submitter : Dr. Derek Holycross

Organization : Provena United Samaritans Medical Center

Category : Health Care Professional or Association

Date: 09/13/2005

Issue Areas/Comments

GENERAL

GENERAL

The proposed changes to the reimbursement under OPPS will severely impact the care of oncology patients in the Vermilion County Illinois area. This change could either force the closure of our outpatient regional cancer clinic or greatly reduce the level of services and drugs we are able to offer.

Submitter : Dr. Jon Isaacson

Organization : Penn State Milton S Hershey Medical Center

Date: 09/13/2005

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

September 13, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates: CMS-1501-P

Dear Centers for Medicare and Medicaid Services:

On behalf of Penn State Milton S Hershey Medical Center we would like to submit the following comments on the proposed rule CMS-1501-P. We were pleased to have seen an increase in payment for cochlear implantation in the 2005 calendar year. However, the 2006 proposed decrease in payment under the outpatient prospective payment system (OPPS) is less than our hospital?s cost to acquire a cochlear implant device and provide associated surgical services. We are concerned that payment for cochlear implantation has not been accurately calculated and is not representative of the costs of the device and procedure. Accurate external device cost data as determined by The Lewin Group study needs to be used to recalculate the relative weight of APC 0259.

Because the cost of surgery continues to exceed reimbursement for cochlear implantation, our hospital has limited the number of surgeries we have been able to perform. Although our program has been in existence since the mid 1990s we have actually had to reduce the number of new implants we are performing over the years due to insurance reimbursement issues. This reduction is despite the absence of a decline in the population in our area in need of cochlear implantation services. The cost effectiveness and the extraordinary benefits provided by cochlear implants to Medicare patients with severe to profound hearing loss is well documented and experienced regularly by us first hand. CMS needs to ensure that the number of centers and clinicians able to provide cochlear implant services to Medicare patients is not further limited by a reduced level of reimbursement.

Based upon the proposed rate decrease, it is anticipated that our hospital will lose money on every Medicare cochlear implant surgery in 2006. Combined with the anticipated loses for Medicaid patients, this may force our program to close its doors. We ask CMS, if nothing else, to set the 2006 OPPS payment no lower than 100% of the 2005 payment rate plus the inflation and other update factors applied to all APCs.

Penn State Milton S Hershey Medical Center appreciates the agency?s recognition of the potential impact of payment rates on access to care and hopes that you will consider carefully the comments and recommendations we have submitted. If you require further information, please do not hesitate to contact the Audiology and/or Otolaryngology Departments at 717/531-7171.

Sincerely,

Erica D Colt, AuD
Michele L Gerrish, AuD
Jon E Isaacson, MD
Julie A Rhoades, AuD

Submitter : Mrs. Nancy Muller

Organization : National Association For Continence

Category : Consumer Group

Date: 09/13/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-379-Attach-1.DOC

National Association For Continence
62 Columbus Street
Charleston, SC 29403
14 September 2005

Mark McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-1501-P
Room 445-G, HHH Bldg
200 Independence Avenue SW
Washington, DC 20201

Electronic correspondence: http://www.cms.hhs.gov/regulations/ecomments

Re: File Code CMS-1501-P (42 CFR Parts 419 and 485)

Dear Dr. McClellan:

I am writing with commentary on the above referenced announcement appearing in the Federal Register (Vol. 70, No. 141/July 25, 2005) regarding the proposed changes to the Hospital Outpatient Prospective Payment System (OPPS) and Calendar Year 2006 Payment Rates under the Medicare Program.

First, allow me to acknowledge and thank you for your efforts in managing the very difficult task of juggling the demands of patients for coverage, the demands of providers – facilities and healthcare professionals alike – for reimbursement, and the demands of advocacy groups such as ours for access to medical technology and innovations, all against a backdrop of what is an ever-restrictive budgetary environment. You must feel, at times, as if you are working with one arm tied behind your back. I commend you for your diligence and your dedication to addressing these complex and often conflicting issues and perspectives.

As Executive Director of the National Association For Continence (NAFC), I speak on behalf of an estimated 25 million adult Americans who routinely experience incontinence, or the loss of bladder or bowel control. As a 501 (c) 3 corporation in existence nearly a quarter of a century, we seek to educate the public, disseminate information about treatment and management options, and advocate on behalf of those with incontinence, voiding dysfunction, and/or related pelvic floor disorders. NAFC is the world's largest and most prolific such organization in this field of healthcare. The organization's activities are broadly funded by individuals, industry, and private foundations.

While I will not pretend to have expert knowledge of the intricacies of how the OPPS is designed, I must express my concern that the consequences of a structure that essentially relies on claims data from hospitals, rather than actual "real world" data, and on data that lags by two years are that hospitals can find themselves with a strong economic disincentive to offer certain

innovative therapy for patients. Continued access for Medicare beneficiaries – and thus for all consumers insured under private pay insurance that takes its cue from Medicare policies – is at stake. Among other contaminants to the current system is the fact that hospital contracts with managed care organizations often specify discounts on devices, supplies, and services that shape hospital billing in such a way that claims data may be distorted. By law, of course, CMS cannot be charged by a hospital more than non-Medicare patients are billed for such items, essentially placing a ceiling on how a hospital's pricing and thus revenue sources are structured.

For example, the proposed CMS payment for an implanted device mapped to APC 0222, using claims information only and without adjustment as in the past, will result in a $2,630, or 21.3% decrease from prior levels. With such a substantial decrease, not offset in this case by the $400 increase proposed on an integral, companion device used in the surgical procedure and pegged to APC 0040, it is likely that hospitals will be forced in the future to refuse to offer the therapy utilizing these items, as they cannot sustain themselves economically with such a gap between how they are paid and their own outlays for supplies, equipment, staff, and medical devices. Nor is it realistic to expect that sufficient cost cutting can occur within industry as quickly as needed to close the gap with its own voluntary price decreases. What remains becomes an untenable situation.

Such is the case for the Medtronic Interstim® device. At present, it is the only globally established and proven means of satisfactorily treating urge urinary incontinence with a return of quality of life to patients not responsive to more conservative therapies with behavioral and pharmacological intervention or for whom prescription drugs are not appropriate. There are an estimated 9-13 million adult Americans with such symptoms, a small fraction of whom are suitable or ideal candidates for Interstim. With over 50,000 such implants around the globe of Interstim and nearly as many success stories from their host recipients and their surgeons, it will be catastrophic for those not yet reached if this therapeutic option is denied by the flaws of a system for structuring payments by CMS to America's hospitals.

In addition, the device is being implanted successfully in patients suffering from interstitial cystitis, a chronic condition of severe inflammation and painful ulceration of the bladder lining. This disabling condition affects approximately one million adults, the large majority of whom are young to middle-aged women. Interstim is also being researched and evaluated for the treatment of fecal incontinence caused by severe bowel spasms. There are precious few options available to such individuals, and without access to such advancing technology, despondency, social isolation, and even suicide become real risks. Should the available urinary incontinence market for Interstim collapse, these patients too will likely be robbed of access to the technology, as it may not remain feasible for Medtronic to continue to market and support the device in the U. S. for such relatively small, fringe applications.

Because of the coding system used by CMS, I would not be surprised if this example is also repeated for other devices, again threatening access to proven therapies. I understand from correspondence with others that many of the APCs are not receiving a reimbursement level that recognizes the full costs of the devices and other resources required to perform these in-hospital procedures. In addition, a number of device-related APCs have been underpaid under OPPS since its commencement.

Unless alternative methods are devised to calculate payment levels, Interstim and possibly other such innovations will soon disappear from our landscape. Please let me know how I might assist you with the prioritization that this subject warrants, including providing you with patient or physician testimonies that you might find relevant.

Sincerely and with regards,

Nancy Muller
Executive Director

Submitter : Dr. Gary Mazzanti

Organization : Shreveport Hyperbaric & Wound Care Center

Category : Physician

Date: 09/13/2005

Issue Areas/Comments

GENERAL

GENERAL

Dear CMS,

Once again you have the opportunity to provide good direction for positive outcomes medicine saving tens of thousands of dollars in related amputation and rehabillitation cost. The Appligraph and Dermagraf products provide a clinically excellent and cost effective approach to dealing with the lower extremity diabetic ulcer. You yourself conducted a study that highlights the needs for more agressive and effective treatments for millions of affected diabetic patients. Reduction in reimbursement is a sure and constant way to limit these biological options to treat and heal these patients. It is proven time and time again that good products, research and development is met with reductions in reimbursements driving the price down and the utilization down further. In my medical opinion, I have had great successes with these products, they are time consuming pruducts to apply and manage, there must be adaquate reimbursement for both the product and the physician so that the patient can recieve the benefit of these products. I ask you to please compare the relatively minor expense of these limb saving products to the astronomical cost of amputation and rehabilitation. I venture to say that if you drove the cost of amputation down, there would most certianly be more effort made towards limb salvage. Please consider the medical effacacy that these products offer to a diabetic population that you have recognized as a leading cause of death, amputation and rehabilitation in the US. By raising the reimbursement, you also rais eht eawareness and utilization of such treatment modalities and thus save millions from unnecessary amputations and costly long term hospital treatments. As a Wound Care Specialist, challenged to save the limbs of these patients, I have certianly seen the many benefits that this treatment modality provides. Reducing reimbursement would most certianly effect that utilization. I sincerely hope that your research and efforts over the last 5 years to improve the plight of with lower extremity wounds is not just rhetoric. Your efforts to reduce this modality would most certianly increase the loss of limbs.

In summary, I feel as a Medical Doctors providing valued wound care to hundres of patients, the reduction of reimbursement is not necessary, and most certianly would damage the industry which provides alternative treatments to amputation. Please do not decrease this reimbursement.

Thank you

Gary B. Mazzanti, M.D.
Medical Director
Shreveport Hyperbaric & Wound Care Center
Maintaining a 93.5% heal rate with the help of Appligraf and Dermagraf

Submitter : Ms. Anne Dill

Organization : Compass Healthcare Inc.

Category : Health Care Industry

Date: 09/13/2005

Issue Areas/Comments

GENERAL

GENERAL

Our agency Alexandria Wellness is a freestanding community mental health center in Alexandria. We serve approximately 300 patient on an annual basis. We employ approximately 15 contract workers in our community. We provide intensive psychiatric programs that are much needed by the patients in our community.

For example we have helped numerous patients who were unable to leave home or shop for themself. Since participation in our program they are now able to go shopping, established routine healthcare and grooming needs and now have a stronger support base which.

We are requesting the proposed 15% cut for our program be stopped. The current payment rate is not sufficient to cover the costs needed for our intensive programs. Our costs are higher than hospitals who can share and spread their costs to other departments. Our paitent acuity level is also more intense than the hospital patients receiving one or two therapy sessions.

This service is especially needed for our rural communities who are not serviced by hospital programs. Additionally our state does not offer this program as a Medicaid service.

Please consider not cutting the Partial Hospitalization Program cost so drastically when most outpatient costs are receiving a 3.5% increase in payment rates.

Submitter : Ms. Christine Goulet

Organization : ACENTA

Date: 09/13/2005

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

I am disturbed to hear about the proposed reduction in payment for cochlear implantation after receiving the good new about the increased payment. Cochlear implants provide exceptional benefit to patients with severe loss who cannot benefit from hearing aids. Cochlear implants are cost effective and make life easier for the implantee and those communicating with the implantee. As it is, only a limited number of clinics across the US provide cochlear implant services. If medicare continues to cut rates, centers will not be able to provide such a beneficial and successful service. If payment is cut less patients will be able to receive cochlear implants. Please set the 2006 OPPS payment no lower than 100% of the 2005 payment rate plus inflation. I want patients to be able to access care and appreciate your attempts to make cochlear implantation a viable option to patients. CMS should substitute accurate external device cost data as determined by the Lewin Group study and recalculate the relative weight of APC 0259. Thank you for the time. Please consider revising the rate and not lowering payment for cochlear implant reimbursement.

Submitter : Dr. Gerit Mulder

Organization : University of California San Diego Medical Center

Category : Physician

Date: 09/13/2005

Issue Areas/Comments

GENERAL

GENERAL

Please correct the 2006 reimbursement rate for Apligraf and Dermagraf to the initial proposed payment rates for calendar year of 2006.

Submitter : Dr. Neil Stein

Organization : Metro Urology

Category : Physician

Date: 09/13/2005

Issue Areas/Comments

GENERAL

GENERAL

The reimbursement rates do not cover the cost of prostate cryotherapy. I do approximately 6-8 per year. It was only with difficulty that I was able to get our hospitals to agree to do the procedure. If reimbursement does not cover the hospital cost, then patients will not be able to be offered prostate cryotherapy. In addition, cryotherpay could be offered in an ambulatory center (surgicenter) at a lower cost, if medicare would reimburse the facility enough to cover the cost of the procedure.

Submitter : Ms. Jane Hyatt Thorpe

Organization : AdvaMed

Category : Health Care Provider/Association

Date: 09/13/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-385-Attach-1.DOC

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

September 13, 2005

Via Electronic and U.S. Mail

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room 445–G, HHH Bldg
200 Independence Ave., SW
Washington, DC 20201

Re: Hospital Outpatient Prospective Payment System Proposed Rule (CMS-1501-P) Update for Calendar Year 2006

Dear Dr. McClellan:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Service's (CMS) Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2006 (CMS-1501-P, *Federal Register*, Vol. 70, No. 141, Monday, July 25, 2005, p. 42674). AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

AdvaMed appreciates the considerable effort you and your staff have put into the development of the hospital outpatient prospective payment system (OPPS). We also appreciate your release of the 2004 outpatient hospital claims database and willingness to work with us to preserve beneficiaries' access to the full range of treatment options in the outpatient setting. AdvaMed is committed to a system that ensures that relative weights and payment rates under OPPS include sufficient resources to account for the costs of the medical technologies associated with hospital outpatient procedures and to assure Medicare beneficiaries have access to these technologies in the outpatient setting.

We will comment on the following topics raised by the proposed 2006 OPPS Rule:

- Support for CMS's stated commitment to ensure Medicare beneficiaries have timely access to new technologies including the expansion of CMS's interpretation of the requirements for pass-through payment categories and CMS's willingness to create new pass-through categories.
- Request that CMS set the floor on the proposed payment rate reductions for CY 2006 at 100% of the 2005 payment rates plus the market basket update for device-related APCs (including those device-related APCs not set forth on Table 15).
- Recommendations relating to CMS's determination of device-related APCs.
- Recommendations to appropriately capture device and technology costs in APC rates through the use of device category "c-codes;" educate hospitals on billing and coding for devices and technology; incorporate external data in determining costs; use single and multiple procedure claims in rate-setting; use only correctly-coded claims in rate-setting; and evaluate median cost data based on a sampling of hospitals.
- Recommendations to address charge compression.
- Recommendations relating to the movement of procedures from New Technology APCs to Clinical APCs.
- Recommendations specific to certain APC rates, including: providing descriptions and explanations of all changes; status indicator change for CPT Code 76937; status indicator change and APC assignment for HCPCS Code 0069T; status indicator change and APC assignment for 0054T, 0055T, and 0056T; and calculation of blood and blood product-related procedure rates, especially low volume procedures.
- Recommendation to remove the proposed AMA CPT Code requirement for New Technology APC applications.
- Recommendations concerning multiple procedure discounts.

I. Access to New Technology and Pass-Through Device Categories

AdvaMed appreciates CMS's stated commitment in the proposed OPPS Rule for 2006 to ensure Medicare beneficiaries have timely access to new technologies. Towards that end, we commend CMS for soliciting comments on the criteria related to pass-

through eligibility and applaud CMS's recognition that a traditional definition of surgical incision limits access to innovative, less invasive technologies that can be inserted through an orifice. These technologies offer benefits for Medicare beneficiaries and avoidance of more invasive, costly surgery. We believe this change will allow access to innovative and less invasive technologies – especially in the areas of gynecologic, urologic, colorectal and gastro-intestinal procedures – that meet the other stringent requirements for pass-through payment.

By way of implementation, CMS proposes to modify its current interpretation of the regulations (set forth at 42 C.F.R. § 419.66(b)(3)) to consider devices pass-though eligible if inserted or implanted through a natural or surgically-created orifice within the scope of surgically implanted devices, as well as those that are inserted or implanted through a surgically created incision. While this interpretation resolves the need to establish the existence of a traditional surgical incision to insert/implant a device through an orifice, we suggest that regulatory language be modified to institutionalize this change. The current language reads:

> *Sec. 419.66 Transitional Pass-through Payments*
>
> *(b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.*

AdvaMed respectfully requests that the language in the regulations be changed as follows:

> *(b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is implanted or inserted, through a natural or surgically created orifice or through a surgically created incision, whether or not the device remains with the patient when the patient is released from the hospital.*

AdvaMed also support CMS's willingness to create new pass-through device categories where an existing or previously existing category descriptor does not appropriately describe the new type of device. As AdvaMed has noted in the past, Congress intended to provide access through transitional pass-through payments to new and beneficial implantable devices. We believe CMS has sufficient documentation on devices in expired categories to differentiate them from new devices, and authority to clarify the definitions of previous categories to distinguish them from appropriate new categories.

II. CMS Should Set the Floor on CY 2006 Rates at 100% of the CY 2005 Rates Plus the Market Basket Update for Device-Related APCs Subject to Proposed Payment Rate Reductions

We do appreciate the efforts that CMS has made and are encouraged to see that the proposed rates for some device-related APCs will increase. However, we believe that the proposed 85% floor on payment rate reductions results in too much of a decrease in value for those device-related APCs whose medians were adjusted. Many of the APCs that are subject to the adjustment to 85% of the medians used to calculate the proposed 2006 payments have experienced decreases in rates from prior years and even in 2005 are not receiving a reimbursement level that recognizes the full costs of the devices and other resources required to perform these procedures. Also, a number of device-related APCs have been underpaid from the start of the OPPS. We are concerned that the continued reductions proposed for CY 2006 will prevent many hospitals from covering their costs, translate into significant losses for those hospitals that perform more of these procedures, and lead to access problems for beneficiaries.

For the last two years, CMS has established a floor on payment rate reductions to ameliorate the payment reductions. However, these floors are not nearly adequate to counteract CMS's reliance on inadequate data. This will continue to be a significant problem that will be exacerbated by CMS's intention to discontinue use of a payment reduction floor for future year's payment rates. The table set forth below illustrates the significant payment reductions that have been imposed on several device-related procedures since 2002.

APC/Description	**2002**	**2003**	**2004**	**2005**	***2006***	***Change***
0039 – Implantation of Neurostimulator (Neurostimulator)	$15,489	$11,876 -23.3%	$12,832 8%	$12,532 -2.3%	*$10,765* *-14.1%*	*-30.8%*
0087 – Cardiac Electrophysiologic Recording/Mapping (3-D Recording and Mapping System)	$2,670	$2,504 -23%	$2,172 6%	$2,122 -2%	*$1,822* *-14.1%*	*-31.7%*
0107 – Insertion of Cardioverter-Defibrillator (ICD pulse generator only)	$19,428	$17,013 -12.4%	$18,394 7.5%	$17,963 -2.3%	*$15,431* *-14.1%*	*-20.5%*
0108 – Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads and Pulse Generator (ICD system)	$29,360	$23,131 -21.2%	$24,700 6.4%	$24,121 -2.3%	*$20,721* *-14.1%*	*-29.4%*
0674 – Cryoablation of the Prostate (Probe, cryoablate)	$7250 - $7750 ($2750 + pass-thru of $4500-$5000)	$7781-$8281 ($3281 + pass-thru of $4500-$5000) 6.8%	$6545 -20.9%	$6392 -2.3%	*$5684* *-11.0%*	*-26.6%*

As such, AdvaMed urges CMS to set a floor on the 2006 device-related APC rates at no less than 100% of the 2005 rates plus the market basket update for all device-related

APCs. Although this will not alleviate the unsustainable reductions many devices have experienced over the past several years, it will provide a greater level of continuity.

III. Device-Related APCs

AdvaMed is also concerned about other device-related APCs that CMS did not include in Table 15. Many of these are proposed to receive significant reductions and do not benefit from the protection of the payment floor. For example, the APCs for brachytherapy procedures are all defined by the FDA to be device-related since they require a radioactive source, but they do not appear on Table 15 (APCs 312, 313 and 651). Of these, APC 651, Complex Interstitial Radiation Source Application, is scheduled to receive a 42.3% reduction in payment rate and is currently not eligible for the 85% floor because it is not included on Table 15.

APC 112, Apheresis, Photopheresis and Plasmapheresis, is another example of a device-related APC not listed on Table 15 that should be included as a device-related APC and subject to the payment reduction floor. APC 112 includes three HCPCS codes:

- 36522: Extracorporeal photopheresis;
- 36515: Therapeutic apheresis with extracorporeal immunoadsorption and plasma reinfusion; and
- 36516: Therapeutic apheresis with extracorporeal selective adsorption or selective filtration and plasma reinfusion.

All three procedures utilize device systems to modify or selectively remove agents from blood and return that blood to the patient. These device systems are major cost components and integral to the procedures. We believe the agency's proposed 25.25% reduction of the payment rate for APC 112 (from $2,127.26 to $1,590.08) is excessive and is likely to result in reduced access by patients to important therapy covered by this APC and undue pressure on providers who perform the procedure.

AdvaMed encourages CMS to include these and other similar APCs that will be identified by our members in the list of device-related APCs and where applicable apply the payment reduction floor to them. As noted above, we believe this floor should be set at 100% of the 2005 rates plus the market basket update for all device-related APCs. Again, although this will not alleviate the unsustainable reductions these device-related APCs have experienced, it will at least impose some limitation on the significant reduction in the payment rates from 2005 to 2006 and provide some stability.

IV. Continuing Insufficiencies in Claims Data and Appropriate Coding and Capturing of Device Costs and Charges for Device-Related APCs

A number of factors – the lack of hospital C-code reporting and hospital education on coding and billing, CMS's decision not to incorporate external data into its rate-setting

processes for 2006, CMS's heavy reliance on "single procedure" claims and insufficient data levels, CMS's decision not to use correctly coded claims, and CMS's omission of any discussion of charge compression – are all contributing to significant APC rate variations from year to year. Although CMS indicated in the proposed OPPS Rule for 2006 that the presence of C-code data in the CY 2005 claims will improve data for setting CY 2007 rates, AdvaMed believes that the irregular reporting of C-codes by hospitals is only one factor contributing towards the continuation of inaccurate data on which CMS is setting payment rates. While AdvaMed recommends that CMS address the payment inadequacies for CY 2006 by setting a floor at 100% of the CY 2005 payment rates for all device-related APCs that would otherwise experience a payment decrease, AdvaMed strongly urges CMS to take into consideration the following methodologies to improve payment rate calculations as the OPPS payment structure continues to mature.

Please note, however, that AdvaMed members will be submitting comments about specific APCs and requesting that CMS apply a variety of methods to the rate-setting calculations, including some of those methods set forth below. Where our members provide more detailed information and recommendations to appropriately adjust APC payment rates to more adequately reflect the actual costs of a procedure and related device, we respectfully request that CMS seriously consider their comments. The application of some of these methodologies may result in the increase of the CY 2006 payment rate above the CY 2005 rate and in those instances, application of the payment reduction floor will not be necessary.

A. Mandatory C-Codes

AdvaMed continues to support the mandatory reporting of all C-codes and related incentives to encourage hospitals to be more vigilant in reporting the total charges of performing device-related services. However, we wish to make it clear that while we support mandatory reporting of all device category C-codes, we recognize that there may be some procedure codes for which edits should not be established. For example, certain procedure codes may or may not involve the use of a device. In those instances when a provider submits a claim for a completed procedure that did not involve a device, it clearly would be inappropriate to have an edit in place that would send the claim back to the provider for inclusion of a device category C-code.

Although edits may not be appropriate in all instances, CMS nonetheless must make it clear to providers that the absence of an edit does not relieve them of their responsibility to report the appropriate device category C-code whenever a procedure is performed that does involve the use of a device described by one of the device category C-codes. Toward this end, we urge CMS to strongly consider comments from AdvaMed member companies on the device edits posted on the CMS web site. We believe the October 2005 edits will help to differentiate procedures requiring C-codes versus those procedures that may not require that C-codes be reported to reflect devices.

Requiring that all C-codes be billed and returning improperly coded claims will encourage hospitals to be more vigilant in reporting the total charges for performing device-related services. As such, AdvaMed urges CMS to continue the mandatory reporting of C-codes until a better methodology for collecting device data is in place.

B. Educating Hospitals on Device and Technology Billing

We urge CMS to accelerate its efforts to educate hospitals on the importance of accurate coding for devices and other technologies. In addition to using C-codes, hospitals should be educated on how to report charges for those devices and technologies utilized in the outpatient department that do not have a special C-code designation or special HCPCS coding. For example, there should be clear instructions for consistent utilization of revenue codes. Accurate reporting of device and technology charges will ensure that these items' charges are included in future year's rates for outpatient services.

C. Utilizing External Data

During its February meeting, the APC Advisory Panel recommended that CMS address the problem of missing device data by incorporating external data into median cost calculations. A number of AdvaMed member companies provided data to CMS earlier this year, in time to be incorporated into the proposed rates. However, these adjustments were not made. Furthermore, CMS did not indicate in the proposed OPPS Rule for 2006 that it would take external data into consideration as it did in the proposed OPPS Rule for 2005.

When the medians used to calculate future payments fall below the previous year's adjusted medians, or when stakeholders present external data in response to this year's proposed rule that demonstrate the insufficiency of the data used to calculate the proposed payments or the insufficiency of the proposed payment rate, AdvaMed recommends that CMS make adjustments that more accurately represent the cost of performing the device and technology-related services, including the incorporation of external data provided by manufacturers and other stakeholders into the median cost calculations.

For example, the proposed 2006 payment rate for APC 674, Cryoablation of the Prostate, is not sufficient to cover the cost of the procedure. In fact, there is a shortfall of approximately $3,000 between the documented hospital cost to provide the procedure and the 2006 proposed payment rate for APC 674. External data has been submitted to CMS for the past three years illustrating that it costs hospitals over $9,000 to provide cryosurgery of the prostate. There is a very real probability that patient access will be affected as evidenced by the 30 hospitals that have cancelled or elected not to initiate a cryosurgery of the prostate program because of low Medicare reimbursement.

Another example involves CPT 20982, Percutaneous Radiofrequency Ablation of Bone Tumor(s), including CT Guidance. This CPT Code was established in 2004 and assigned to New Technology APC 1557 with a payment rate of $1,850. At that point there

were no hospital claims data available to support the APC assignment and no explanation was given by CMS indicating what data was used to assign CPT 20982 to APC 1557. For 2006, CMS proposes to keep CPT 20982 in APC 1557 based on 16 single frequency claims available in the CMS data files for 2004. However, the 2006 Physician Fee Schedule CPEP/AMA survey indicates a total procedure cost of $2,914.78. This data demonstrates that personnel and supply costs exceed the assigned APC 1557 payment level without a capital equipment allocation.

Yet another example involves Endovenous Radiofrequency Ablation of Venous Reflux (RFA), which was assigned new CPT codes (36475 & 36476) effective January 2005. RFA also had a C-code in effect until the end of 2004. The decision was made to assign these codes to APC 92 based on clinical similarities within the APC (traditional vein stripping). Unfortunately, the other procedures assigned to APC 92 do not have significant disposables or equipment costs associated with the procedure. Most vein stripping cases have approximately $30 in disposable costs, whereas RFA has a $725 disposable catheter cost plus the costs of additional supplies and capital equipment required to perform the procedure. Thus, the $1538 APC 92 payment rate does not factor in the disposables costs that were previously accounted for via a C-code nor does the rate even closely approximate the total cost for RFA which is approximately $2800.

D. Reliance on Single and Multiple Procedure Claims

AdvaMed remains concerned with CMS's heavy reliance on single procedure claims and reluctance to factor in device-related procedures reported as part of multiple procedure claims resulting in an artificially limited data set. Significant reductions in CY 2006 payment rates for a number of device-related APCs are a direct result of the inaccurate capture of device costs estimated from CMS's single and "pseudo" single procedure claim rate-setting methodology. This is particularly problematic for procedures routinely performed in conjunction with other procedures (*e.g.*, add-on multi-vessel stent codes for intravascular ultrasound, radiation oncology, and brachytherapy) whose costs, by definition, would always be reported on multiple procedure claims, but under single claims methodology are not being captured. For example, CMS is relying on just 111 "single" claims out of a total of 7,041 (1.5%) to estimate median costs for APC 670, Intravascular and Intracardiac Ultrasound. Another example is APC 651, Complex Interstitial Radiation Source Application, where there were 11,963 claims that contained CPT code 77778, however, CMS based the 2006 proposed payment on just 342 claims or approximately 2.8% of the 2004 outpatient claims. As such, AdvaMed urges CMS to create APC payment rates using both single and multiple procedure claims.

E. Use of Correctly Coded Claims

Since the program's inception, CMS has utilized various steps to filter the outpatient hospital claims data, including methods to artificially generate additional "single service" claims. The result has been the capture of more claims, but not necessarily better data. In setting the 2003 and 2004 rates, CMS utilized a C-code screen

that selected correctly coded claims for calculating the medians of about 40 APCs, generally resulting in medians that more accurately reflected the hospitals' costs incurred in performing device-related procedures. We believe that this screening process is evidence that CMS can and should establish rates based on a subset of accurately coded claims.

For example, APC 651, Complex Interstitial Radiation Source Application, includes one CPT code 77778, Interstitial Radiation Source Application; Complex. This interstitial brachytherapy procedure is used to code for prostate brachytherapy, a high volume cancer therapy, as well as other complex interstitial brachytherapy procedures that utilize more than 10 brachytherapy sources per procedure. The 2006 proposed payment for APC 651 is $720.71, which is a 42.3% reduction in the current payment of $1,248.93. Based upon our analysis, it appears that CMS did not use "correctly coded" claims to set the 2006 proposed rates for CPT 77778. If CMS had used claims that contained CPT 77778 and at least one brachytherapy device C-code, the correct code screen yields only 181 claims but the median cost is increased by approximately 18% to $864.54.

Another example involves APC 313, High Dose Rate Brachytherapy. Our claims analysis indicates that approximately 60% of claims did not include the Iridium-192 source C1717 and yielded a median cost of $776.35. However, the 3,442 correctly coded HDR brachytherapy claims had a more accurate median cost of $849.39.

APC 87, Cardiac Electrophysiologic 3- Dimensional Recording/Mapping, is another example of the importance of using correctly coded claims. When the "correctly coded" proxy screen is applied and only claims containing packaged revenue center costs (*i.e.,* device costs) are employed for rate development, the median increases by 81%. This is very strong evidence that the median cost is not accurately represented in the CMS claims data used for rate development of APC 87.

In past years, CMS has used only "correctly coded" claims to determine payment rates. AdvaMed strongly recommends that CMS use only correctly coded claims for all device-related APCs including those that are not set forth on Table 15 in setting payment rates. Although the use of correctly coded claims will not resolve the effect of charge compression (addressed below in Section V), it will result in payment rates that more appropriately reflect the costs associated with these procedures.

F. Improving the Data Used in Calculating APC Median Costs by Developing a Sampling of Hospital Claims Data

AdvaMed recommends that, in consultation with hospitals, manufacturers, and other stakeholders, CMS should consider approaches to collecting, analyzing and utilizing more detailed and accurate cost data from a nationally representative sample of hospitals. Such a sample could be used to validate findings from the larger claims data set and/or to establish median costs that more accurately reflect the costs of providing device-related

procedures and other outpatient services.

One alternative approach would be to conduct a demonstration project that would develop a sample of hospitals (for example, 100-300 hospitals), receiving small grants for set-up and training, to test the feasibility of collecting a valid, reliable and manageable data set from which to develop payment rates.

V. Charge Compression

Under OPPS, payment rates for device-related procedures are based on cost data generated by CMS's cost finding principles. Generally, CMS multiplies charges by hospital-specific cost-to-charge ratios (CCRs) to calculate hospitals' costs for all services in a single revenue center, reducing the charges by a constant factor. This methodology is based on the assumption that each hospital marks up its costs by a uniform percentage within each department to set each service's charge. However, a recent AdvaMed study (previously provided to CMS and attached to this letter for reference) found that hospitals typically have a smaller mark-up for higher-cost devices compared to other items and service. MedPAC's 2003 survey of hospital charge setting practices confirmed that hospitals often use smaller mark-ups on more expensive items. In practice, CMS's methodology does not recognize hospitals' variability in setting charges. If CMS uses a single CCR to estimate costs, the approach will generally lead to an underestimation of hospitals' costs for higher cost items – a phenomenon referred to as "charge compression."

The table[1] below illustrates the variation in mark-up in charges for certain implantable devices in a single revenue center. The mark-up for ICD pulse generators is 79% lower than for other less costly devices, leading to charge compression.

Device Type (from least to highest cost)	Sample Size	Percentage Mark-Up (Mean)
Pacemaker Lead	111	266
ICD Lead	69	221
Pacemaker Pulse Generator	111	221
ICD Pulse Generator	60	142

To the extent that hospitals' mark-up for high cost devices are systematically out of line with the hospitals' mark-up for other items and services, the payment levels for APCs corresponding to these devices are likely to be underweighted and underpaid. The effect on the APC may be especially pronounced when the charge for the device accounts for a high percentage of the total charges associated with an APC, as it would for many

[1] Premier Healthcare Informatics, Perspective Comparative Database for January 1 through December 31, 2004.

implantable devices with high unit costs.

We realize that an issue as complex as charge compression will require coordination and communication between the device industry, hospital industry, and CMS. As such, we recommend that CMS convene a working meeting of representatives from device manufacturers, the major hospital associations, and hospital billing experts to develop proposals to address these issues. We would be happy to assist in the planning of such a working meeting, however, we strongly believe that resolving an issue as complex as charge compression will require CMS leadership and initiative. Not only will addressing these issues improve patient access to life-saving treatments, it will also improve CMS's ability to capture accurate cost data that will result in more appropriate payment rates.

In addition, we offer the following alternative mechanisms that CMS might consider to address the impact of charge compression on payment rates. Although none of these are new, and in fact, AdvaMed and its members have presented them to CMS through the course of various meetings in the last several years, we continue to believe that each of them has the potential to alleviate the problems associated with charge compression. These alternatives involve changing hospital cost accounting systems to separate out high-cost devices, or comparing CMS "cost" estimates off the claims to external data on costs and developing a correction factor to adjust the CMS CCRs for application to high-cost devices. Please note that these proposed alternative mechanisms were also set forth in a letter to Herb Kuhn, Director, Center for Medicare Management, dated September 13, 2005, pursuant to his request.

A. Establish a New Cost Center Solely for High-Cost Devices and Calculate the Appropriate CCR

Using this mechanism, the lower mark-up on high-cost devices will (eventually) become evident via CMS hospital cost reports. Although the impact of this will take several years to come to fruition, long term it will allow CMS to calculate and apply a more appropriate CCR to the high-cost devices resulting in payment rates that more accurately reflect the costs of these devices.

B. Conduct a Study to Determine a Correction to the CMS CCR for High-Cost Devices

If CMS is not willing to establish a new cost center as set forth above, perhaps a representative sample of hospitals would be willing keep their books with a sub-cost-center level for high-cost devices. CMS could then estimate a more appropriate CCR for high-cost and other devices based on the sub-cost-center level for these hospitals. For example, if the hospitals' accounting indicates a CCR average of .3 for low-cost devices and .6 for high-cost devices, and finds that share of device costs is 50/50, then the higher CCR should be used to calculate an adjustment for records for procedures that must use high-cost devices.

C. Incorporate External Data

As previously discussed in Section IV(C), CMS should always accept external data to validate its data and incorporate external data into its calculations in cases where there is insufficient claims data to set appropriate payment rates. This is especially important in cases where estimated acquisition costs substantially exceed estimated average cost from CMS data. CMS should adjust cost estimates based on this data on a case by case basis.

D. Calculate a Charge De-Compression Factor

Based on CMS data (obtained as set forth in paragraph B above or a similar manner) and external data, CMS could estimate the "mark-up function" from charges on claims and device acquisition cost data and incorporate this data into setting the CCRs – one for low-cost devices and one for high-cost devices. Applying a higher CCR to high-cost devices will result in a payment rate increase while at the same time applying a lower CCR to low-cost devices will likely result in payment decreases because the CCRs applied will more accurately reflect the actual costs of the devices.

VI. Moving Procedures from New Technology APCs to Clinical APCs (Other New Technology Services)

The proposed OPPS Rule for 2006 moves a number of device-related procedures from current New Technology APCs into clinical APCs (10 of which are highlighted in Table 11). AdvaMed continues to be concerned that half (5 out of 10) of the procedures in Table 11 will be moved to lower-paying APCs, many significantly lower compared to their 2005 rates. Our analysis of one of the affected APCs suggests that hospitals have only reported the device portion rather than the combination of device and procedure, which is critical if accurate rates are to be established when moving a procedure from a New Technology APC to a clinical APC. These inappropriate reductions will not only affect access to these new services, but could have a negative effect on other new technology in the pipeline. We recommend that CMS re-examine these procedures, and consider options that would prevent reductions in payment, including moving them into different APCs, utilizing external data for rate-setting purposes, and/or allowing them to continue in their current New Technology APC for another year. Furthermore, we urge CMS to apply the floor on the payment reduction that is applied to device-related APCs to procedures that are being transitioned from New Technology APCs to clinical APCs.

For example, CMS proposes to move HCPCS code C9713, Non-contact Laser Vaporization of Prostate, including Coagulation Control of Intraoperative and Post-operative Bleeding, from New Technology APC 1525 to the newly created APC 429, Level V Cystourethroscopy and other Genitourinary Procedures. This new technology service code was created in April 2004, meaning that CMS is basing its APC shift on less than nine months of claims data. While CMS has the authority to move new technology procedures out of New Technology APCs this quickly, it traditionally has allowed claims data from a longer period of time to be used before assigning new technology services to

clinically appropriate APCs. At the August 2005 APC Advisory Panel, a presentation was made on this issue by a device manufacturer, with several Panel members reporting that their hospitals were incorrectly coding these procedures. While the Panel ultimately agreed with CMS's proposal, the discussion raised serious questions about the accuracy of the claims data and the confusion among hospitals billing these procedures. If CMS finalizes this proposal, the payment rate for C9713 will fall by about 33%, from $3,750 to $2,511. AdvaMed is concerned this large cut may prompt patient access concerns. As such, AdvaMed urges CMS to keep HCPCS code C9713 in New Technology APC 1525 for at least one more year to allow for more claims data to be collected before assigning this procedure to a clinically appropriate APC.

VII. Other Device-Related APC Issues

A. Providing Descriptions and Explanations of All Changes

We note that some HCPCS codes were moved to different APCs without a discussion in the preamble providing a description and explanation for the changes. Also, the disposition of a number of Panel recommendations were not discussed. In the future, we urge CMS to include in the preamble a discussion of these changes to allow stakeholders to provide more constructive feedback during the comment period.

B. Status Indicator Change for CPT Code 76937

In the proposed OPPS Rule for 2006, CMS states that for 2006, CPT Code 76937, Ultrasonic Guidance for Vascular Access Requiring Ultrasound Evaluation of Potential Access Sites, Documentation of Selected Vessel Patency, Concurrent Realtime Ultrasound Visualization of Vascular Needle Entry, with Permanent Recording and Reporting, continues to be assigned a status-indicator of N, thus bundling the payment for this separate ultrasound study. This proposal is in direct conflict with a decision made by CMS in the 2003 Final OPPS Rule. In the 2003 Final Rule, CMS proposed to accept the recommendations of the APC Panel and provide separate payment in 2003 for all radiology guidance codes designated as "N" in 2002.

To ensure that Medicare beneficiaries have access to safe, high quality care, AdvaMed recommends that the Status Indicator assigned to CPT 76937 be changed to an "S" allowing for separate payment of this service when provided in the hospital outpatient setting and that CPT 76937 be assigned to APC 0268, Ultrasound Guidance Procedures, as the resources needed to perform CPT 76937 are comparable to the resources needed to perform CPT code 76946 or 76965, which are both cross-walked to APC 0268.

C. Status Indicator Change and APC Assignment for HCPCS 0069T

AdvaMed is concerned with the current outpatient reimbursement for the technical component of correlated audioelectric cardiography (HCPCS 0069T). In the 2005 Final Rule correlated audioelectric cardiography, described as "Accoustic Heart Sound

Services," was incorrectly assumed to add minimal additional cost above the cost of an ECG test (HCPCS 93005) which is performed at the same time. As a result, HCPCS 0069T, the technical component of the correlated audioelectric cardiography procedure, was assigned a status code of "N - Items and Services packaged into APC Rates" and was bundled into the payment for ECG (APC 99 with a proposed 2006 national payment of $22.58). In actuality, the cost to a hospital to perform correlated audioelectric cardiography is significantly greater than even the cost of performing the ECG itself. In order to quantify the cost differential, an AdvaMed member worked closely with several hospitals to calculate their cost to perform a correlated audioelectric cardiography test as compared to an ECG test. Based upon the analysis, it was determined that the cost for performing an ECG test is estimated to be $31.23. The analysis determined that a hospital's cost of performing a correlated audioelectric cardiography test is $54.95 which exceeds the cost for ECG by $23.72 per procedure.

Furthermore, we reviewed the median cost data used to establish the proposed 2006 APC payments (spreadsheet file "median_apc_1501p.xls" obtained from CMS website). The spreadsheet identifies the "True Median Cost" for APC 99 (the APC for ECG, HCPCS 93005) as $23.06. When we compared the estimated cost of a correlated audioelectric cardiography test, it exceeded the median cost by approximately 2.4 times. We also compared the cost of a correlated audioelectric cardiography test to the lowest median cost service within APC 99 (HCPCS code 93041 as defined in hcpcs_medians_1501p.xls obtained from CMS website) in accordance with section 1833(t)(2) of the Act and found that the cost of correlated audioelectric cardiography exceeded the "True Median Cost" of HCPCS 93041 by 4.09 times.

AdvaMed respectfully requests, that in order to establish equitable reimbursement for hospitals, that CMS modify the status code for 0069T from "N - Items and Services packaged into APC Rates" to status "S - Significant Procedure, Not Discounted when Multiple" to allow the HCPCS code to be mapped directly to APC 99. In doing so, hospitals would be able to receive a separate APC payment for the performance of a correlated audioelectric cardiography procedure.

D. Status Indicator Change and APC Assignment for 0054T, 0055T, and 0056T Computer assisted Navigation for Orthopedic Procedures

AdvaMed is concerned that CMS has not established hospital outpatient reimbursement for computer assisted navigation for orthopedic procedures described by CPT codes 0054T, Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure, with Image-Guidance Based on Fluoroscopic Images; 0055T, Computer Assisted Musculoskeletal Surgical Navigational Orthopedic Procedure, with Image-Guidance Based on CT/MR images; and 0056T, Musculoskeletal Surgical Navigational Orthopedic Procedure, Imageless, by assigning these codes to the appropriate APC.

Computer assisted navigation procedures is a class of technologies currently recognized and paid using CPT Category I and Category III codes. The Category I code

includes brain and spine procedures and is described by CPT code 61795, Stereotactic Computer Assisted Volumetric (Navigational) Procedure, Intracranial, Extracranial, or Spinal. For 2004, CPT created Category III codes for a more accurate representation of orthopedic procedures. We think it's important to emphasize that the spinal computer assisted navigational procedures can be viewed as a subset of "computer assisted navigational orthopedic" procedures in that there is a common technological theme and comparable technological resources associated with the entire class of computer assisted procedures.

CMS has properly recognized and assigned CPT 61795 to APC 302 with a proposed payment of $272. Unfortunately, 0054T, 0055T, and 0056T have been overlooked. Accordingly, we request that CMS assign the "orthopedic" computer assisted procedures to the same APC as computer assisted spine procedures (*i.e.*, APC 302) or establish a new APC which would include all the computer assisted procedures.

E. Blood and Blood Products

AdvaMed companies produce a broad range of technologies for the collection, testing, safety assurance, processing, storage and transfusion of blood. Our member companies continue to be concerned that low payment amounts for blood products and services will challenge hospitals' abilities to assure the availability of safe blood products.

We commend CMS's acknowledgement of the need to protect beneficiaries' access to a safe blood supply and its effort to provide outpatient blood billing guidance through the issuance of Program Transmittal 496. Although we have been hearing questions from hospitals about the transmittal, we believe that such guidance is a significant step toward consolidating and clarifying the blood reimbursement scheme for hospitals.

Notwithstanding, we are concerned about the proposed reductions in certain blood and blood product APC rates for 2006. For example, CMS proposes to pay $161.71 for a unit of leukocyte reduced red blood cells (APC 0954). Last year, the blood collection community surveyed blood centers nationally and found that the median hospital acquisition cost for leukoreduced red blood cells in 2003 was $198. We are concerned that the proposed 2006 rate is inadequate because since 2003, with the introduction of additional blood safety measures, the cost of leukocyte reduced RBCs has steadily increased.

As such, we support the APC Panel recommendation that CMS should use the CY 2005 rates as the floor for blood and blood products and the higher of the 2004 median or 2005 payment rate to set the payment rate. We believe this recommendation is consistent with the comments articulated by the American Association of Blood Banks and the American Red Cross, which we also urge CMS to consider. We also recommend that CMS thoroughly review the comments of AdvaMed member companies, which offer further detail on the blood product and service payment issues raised by the proposed rule and provide a variety of options on how to address these issues.

VIII. Proposed AMA CPT Code Requirement (New Technology APCs)

CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application (for either a Category I or III code) be filed with CMS as a part of the application for a New Technology APC, along with CPT's letter acknowledging or accepting the CPT code application.

AdvaMed is concerned that the AMA CPT Panel may not be an appropriate forum for a federally mandated decision, and may add undue delay to decisions, preventing rapid recognition of new technologies for Medicare beneficiaries. The AMA CPT Editorial Panel is a private organization that is not subject to procedural protections, necessary for public policy making. AMA meetings are closed to the public, the bases for decisions are not available to the public, and there are no voting representatives on the AMA CPT Panel from the medical technology industry and medical technology manufacturers. Furthermore, the AMA CPT Editorial Panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act. Thus, requiring the submission to the AMA CPT Panel risks the involvement of an organization that may not be accountable as are all other agencies that are responsible for federal public policy decisions. Even the requirement that AMA only acknowledge receipt of the application suggests that the AMA has some potential "veto" power over a decision that arises uniquely within CMS's authority. AdvaMed suggests that delegating even this modest function to the AMA may be an unlawful delegation of federal decision making to a private organization.

In addition, the requirement that a CPT application be filed will not provide CMS with input from the medical community unless CMS is proposing to wait until the AMA CPT Editorial Panel has made a coding determination and that determination has been made public. Filing an application neither requires nor guarantees a review by the medical community. As such, the CPT code application will not provide CMS with additional information on the technology being evaluated, beyond what is provided as part of the New Technology APC application process, because the applications are very similar. Moreover, because of the timing of the CPT process, it is not reasonable for CMS to wait until a CPT coding decision has been made public to decide whether to assign a New Technology APC.

Finally, AdvaMed is concerned with CMS's position that either a Category I CPT code or a Category III CPT code application will be acceptable prior to submitting a New Technology APC application. This position fails to take into consideration the significant differences between these two types of codes. Category I codes are typically assigned to a procedure that has become an accepted standard of care thus defeating the purpose of adoption of new technology. If manufacturers are forced to apply for a CPT code before sufficient information is available, it is likely that the CPT Panel would assign a Category III "emerging technology" code that often results in a non-coverage decision by local

Medicare carriers and fiscal intermediaries, as well as commercial payers. Because of the risk of non-coverage associated with Category III CPT codes, manufacturers will be more hesitant to apply for a New Technology APC and a CPT code simultaneously. This will directly result in the use of more miscellaneous codes, decreased ability by CMS to track the use and cost of devices, and ultimately jeopardize beneficiary access.

For each of the reasons set forth above, AdvaMed strongly recommends that CMS not include this proposal in the 2006 Final Rule.

IX. Multiple Procedures

A. Device-Related APCs

When APCs are denoted as having a multiple procedures discount, the hospital receives the full payment for the most expensive procedure and half of the payment for each additional procedure. The discounts are intended to reduce hospital payments to account for efficiencies in staffing, scheduling, procedure room preparation, inter-operative, and other resources. AdvaMed is concerned that the multiple procedure discount is not being utilized properly with respect to device-dependent APCs. For these procedures, where the majority of costs are related to the purchase of the device, performing multiple procedures does not reduce the cost of the devices involved. By inappropriately applying the multiple procedure discount to device-dependent APCs, CMS creates inappropriate financial incentives that penalize hospitals for efficiently providing these services on the same day. We request that CMS assign a status indicator of "S" to device-dependent APCs because the rationale for multiple procedure discounting is not applicable and the use of discounting could serve as a disincentive to efficiently perform multiple device related procedures on the same day.

B. Multiple Diagnostic Imaging Procedures

Currently under OPPS, hospitals receive the full APC payment for each diagnostic imaging procedure for each service on a claim, regardless of how many procedures are performed using a single modality and whether or not contiguous areas of the body are reviewed. CMS proposes that whenever two or more procedures in the same family are performed in the same session, the first procedure will be paid at the full reimbursement level and the second at a discount of 50%.

AdvaMed agrees with the CMS position that, when some of the procedures identified by CMS are performed in the same session, some of the resource costs are not incurred twice. CMS utilized the Medicare Physician Fee Schedule methodology and data, rather than that of the OPPS process in developing this policy. Further, we believe that the hospital's CCRs and related cost-reporting methodology already take into account reductions for multiple imaging procedures. Since the OPPS methodology already accounts for the cost efficiencies of multiple procedures in the same session, an additional 50% reduction, as described in the proposed rule, would contradict this methodology and

systematically disadvantage hospitals relative to other imaging facilities. As such, AdvaMed supports the APC Advisory Panel's recommendation that CMS delay implementation of the multiple diagnostic imaging procedure reduction for one year until further study can be done to analyze the impact of this proposal.

***

AdvaMed urges CMS to carefully consider the comments submitted by our member companies, as they provide a unique source of information in developing appropriate OPPS payment rates. We appreciate this opportunity to submit comments on the July 25, 2005 proposed OPPS Rule for 2006, and look forward to working with CMS to address our concerns.

Sincerely,

_____

David Nexon
Senior Executive Vice President

cc: Herb Kuhn
Liz Richter
James Hart
Joan Sanow

Submitter : **Dr. Walter Hayes** **Date: 09/14/2005**

Organization : **Dr. Walter Hayes**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I would like to comment on the proposed reduction in payments for Apligraft and Dermagraft. I treat patients at a local outpatient Wound Healing Center, and have used these products to save limbs from amputations, thus lowering the overall healthcare costs. Reducing the payments for these items below the acquisition cost of the products to the wound care center would make them unavailable for purchase, thus increasing the amputation rate and overall increasing the healthcare costs. Diabetic foot ulcerations are difficult enough to successfully heal, and without these products in my arsenal, it would be almost impossible. The quicker a limb is healed, the overall cost is reduced, anyone in the wound care field knows this. With Dermagraft and Apligraf, it has been proven in multiple clinical studies to heal these ulcerations significantly faster. A fair reimbursement price should be payed, but not at the expense of a patient's limb.

Respectfully,

Walter W. Hayes, DPM, AACFAS

Submitter : **Mrs. Catherine Meeter** **Date: 09/14/2005**

Organization : **Sutter Health**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

Re: Section II, 4 - Proposed Changes to Packaged Services. Sutter Health would like to comment on CMS' response to a question posted as a FAQ regarding adoption of Appendix G in the CPT book for hospitals relevant to conscious sedation, on 6/9/2005 (ID #4869). Sutter Health respectfully requests that CMS not adopt this as an official policy. Section II. 4 of the proposed rules for OPPS state that packaged services are identified by the status indicator of N. The conscious sedation codes of 99141 and 99142 both are listed with a status indicator of N. The proposed rules in this section go on to state that hopitals include charges for packaged services on their claims and the costs associated with these services are then bundled into the costs for the separately payable procedures on the claims for purposes of median cost calculations. It goes on to state that hopsitals may use CPT codes to report any packaged services that were performed consistent with CPT coding guidelines. I am sure you are aware that the CPT book is created for physicians by physicians. The use of Appendix G makes sense for a physician with the procedures listed because typically the physician doing the procedure is the same physician directing the conscious sedation, i.e. there is no anesthesiologist. A hospital however, must provide a dedicated, independent trained observer to assist the physician in monitoring the patient's level of consciousness and physiological status. They cannot be doing anything else. Other staff would be present to assist the physician in the actual procedure and the hospital would submit the appropriate code for the procedure. It would place an undue burden upon hospitals to charge the conscious sedation codes for some procedures and not others. In light of the fact that these codes are pakaged, please reconsider asking hospitals to deviate from a practice that CMS has adopted, i.e. asking hospitals to report all procedure codes that have an N status indicator.

Submitter : **Dr. Linda Knorr** **Date: 09/14/2005**

Organization : **Knorr Medical Associates**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

The reimbursement rate for Apligraf and Dermagraft is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84
Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

Reimbursement at this rate would jeopardize patient access to the products and would have a negative impact on the nation?s healthcare system.

Just wanted to note the 2006 reimbursement error that we discovered for Apligraf and Dermagraft. Thanks for taking a look at this during your comment period.

Submitter : **Mr. James Matons** **Date: 09/14/2005**

Organization : **BrachySciences**

Category : **Device Industry**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-389-Attach-1.DOC

BRACHYSCIENCES

September 12, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPPS Payment System and 2006 Payment Rates

Issue: New Technology APC

Dear Dr. McClellan:

BrachySciences is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

We would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

New Technology APCs
CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

BrachySciences is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization that is not subject to procedural protections that are required for public policy. AMA meetings are closed to the public and the basis for decisions is not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel has no voting representatives from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions. This requirement may be an unlawful delegation of federal decision making to a private organization.

Category I codes are typically assigned to a procedure that has become an accepted standard of care thus defeating the purpose of adoption of new technology. If manufacturers are forced to apply for a CPT code before sufficient information is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code that often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries, and many commercial payers.

BRACHYSCIENCES

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives of manufacturers on the decision making panel, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiary's full access to high quality care in the hospital outpatient setting just as other patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me.

Sincerely,

James Matons
President
BrachySciences

115 Hurley Road, Building 3C • Oxford, CT 06478 • Tel: 203-262-0571 • Fax: 203-262-8968 • www.brachysciences.com

Submitter : Dr. James Knorr **Date: 09/14/2005**

Organization : Knorr Medical Associates

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The reimbursement rate for Apligraf and Dermagraft is proposed to be 30% below the selling price of the product.

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84
Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

Reimbursement at this rate would jeopardize patient access to the products and would have a negative impact on the nation?s healthcare system.

Just wanted to note the 2006 reimbursement error that we discovered for Apligraf and Dermagraft. Thanks for taking a look at this during your comment period.

Submitter : Mr. RALPH SCHULTE **Date:** 09/14/2005

Organization : Mr. RALPH SCHULTE

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

SEPTEMBER 12, 2005

MARK B. MCCLELLAN, M.D. ,PH.D.
ADMINISTRATOR
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ATTN: CMS-1501-P
P.O. BOX 8016
BALTIMORE, MD 21244-8018
RE: CMS-1501-P

DEAR DR. MCCLELLAN,
THE PURPOSE OF THIS LETTER IS TO INFORM YOU THAT I ELECTED TO HAVE CYROSURGERY OF THE PROSTATE THAT WAS PERFORMED FEB 2, 2005 BY JORGE TORRIGLIA M.D. MI INSTITUTE OF UROLOGY. THE SURGERY WAS PERFORMED AT OAKWOOD HOSPITAL IN DEARBORN, MICHIGAN.THE ONLY INSTITUTION AVAILABLE IN MICHIGAN.BECAUSE OF MINIMALLY INVASIVE PROCEDURE I WAS ABLE TO RETURN TO MY FARM IN NORTHERN MICHIGAN, RESUME CARING FOR MY ANIMALSBY MARCH 1, 2005 AND RIDING MY HORSES IN MAY. IT TOOK ONLY ABOUT 6 MONTHS TO REGAIN 99.9 PERCENT CONTROL OF MY BLADDER. A FRIEND FROM REED CITY MICHIGAN OBSERVED THE SUCCESS I HAD WITH THE PROCEDURE AND OPTED TO HAVE THE SAME PROCEDURE AND DOCTOR. VICTOR SMITH HAD HIS SURGERY JUNE 1, 2005 AND HAD GONE BACK TO WORK FOR A TREE SPRAYER IN JULY. I ALSO GAVE THE INFORMATION TO A PERSON IN TECUMSEH,MICHIGAN. MAY 24, 2005 MY P.S.A. WAS .04FROM .6ON THAT DAY TWO OTHER PATIENTS P.S.A. SCORE WERE .03. WITHOUT THE USE OF RADIATION , ALL OF MY OPTIONS ARE STILL ON THE TABLE IN CASE OF RE OCCURENCE. ACCORDING TO THE NOTICE IN JULY'S FEDERAL REGISTER, THE RATES ARE GOING TO BE REDUCED IN 2006. THIS WOULD BE A GREAT SERVICE TO THE RECIPIENTS. THEREFORE I IMPLORE YOU TO FUND AND ADJUST THE PROPOSED PAYMENT RATE FOR APC674 UPWARD SO THAT MORE PEOPLE CAN BENEFIT FROM THIS GREAT CANCER ABLATION PROCEDURE.

THANK YOU,

MR. RALPH E. SCHULTE
11323 W. JEFFERSON
LAKE, MI 48632
(231)734-5382

Submitter : Dr. Anto Bagic **Date:** 09/14/2005

Organization : University of Pittsburgh

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Please, See Attachment. Sincerely, Dr. Bagic

CMS-1501-P-392-Attach-1.PDF

University of Pittsburgh

School of Medicine
Department of Neurology

Kaufmann Medical Building
Suite 811
3471 Fifth Avenue
Pittsburgh, PA 15213
412-692-4622
Fax: 412-692-4526
E-mail: dekoskyst@upmc.edu

Steven T. DeKosky, M.D.
Professor and Chairman

September 12, 2005

Center for Medicare and Medicaid
Department of Health and Human Services
Attn: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

Re: CMS MEG Reimbursement for the following CPT Codes: 95965, 95966 and 95967.

Dear Madams/Sirs:

The University of Pittsburgh Center for Magnetoencephalography (MEG) is the latest addition to our broad state-of-the-art clinical and research facilities. Its acquisition was motivated by our goal of providing the best possible patient care in a cutting-edge environment, and to remain at the forefront of biomedical research. We wish to improve access to care by bringing advanced MEG technology close to over 35 million residents of Pennsylvania, Maryland, Ohio, West Virginia, Virginia, and western New York. These cardinal intentions may be sustained only if the financial feasibility of MEG use is maintained. This will not be the case if the proposed adjustments in MEG reimbursement levels are implemented. Thus, the Departments of Neurology and Neurosurgery enthusiastically support the August 18, 2005 CMS decision to postpone changes in reimbursement for MEG evaluations until accurate billing data are available. We also strongly support maintaining the current level of reimbursement, since this realistically reflects the expenses associated with MEG studies.

Since the mid-1990s, MEG has been used increasingly in evaluating some of the most challenging cases in epilepsy and neurosurgery. Currently, it is a critical part of the pre-surgical evaluation of the most complicated epilepsy cases, and in patients with brain lesions involving functionally important brain regions. The importance of MEG studies is emphasized by the fact that surgery is the only potential cure for these patients. Inclusion of a MEG study increases the likelihood that a person will be deemed an appropriate surgical candidate, of having a successful surgery, and making the best functional recovery. Improvements in surgical outcomes associated with MEG evaluation will help to make potentially curative therapy a more attractive treatment option to both patients and clinicians.

Some members of our team have evaluated MEG for several years and found it to be of critical value for selected patients. A striking case was a young woman who was worked up very thoroughly in a reputable academic institution, but no epileptic focus was found. She then self-referred for a MEG study, which resulted in her epileptic focus ("surgical target") being clearly defined. She was then deemed a surgical candidate. This is just one example of how MEG can provide critical diagnostic information in a complex case of brain disease.

We are well aware that MEG technology is not a panacea for diagnostic pre-epilepsy surgery evaluations, or for brain mapping in preparation for tumor or other lesion resection. On the contrary, there will be many cases where application of all known methods will not provide the desired answers. Unselective use of MEG would be unnecessary and inappropriate, but as physicians we are obligated both morally and professionally to provide our patients with the best available information and advice. At this point, this undoubtedly includes, where appropriately indicated, application of MEG methods.

MEG is an expensive technology. On top of the $2,000,000 to $3,000,000 initial cost of a system, construction of a magnetically shielded room costs about $400,000 to $500,000, the maintenance contract for the instrument is more than $100,000 a year, and liquid helium costs $30,000 to $50,000 a year. The cost of personnel adds significantly to these numbers. Additionally, the data analysis is frequently laborious and demanding. This is especially the case in MEG localization of epileptic foci (CPT #95965). Frequently analyzing a moderately complex epilepsy case takes much more time than analyzing multiple straightforward studies of evoked magnetic fields (95966 and/or 95967), which also require a significant amount of time. Taken together, these data argue for the necessity of maintaining the current level of reimbursement.

Inadequate reimbursement would severely affect the availability of, and access to, this already restricted but clinically very important technology. Professionally, it would represent a return to medicine of the 20th century, since its advantage over prior technologies is clear. We believe that American citizens and taxpayers do not deserve, and ultimately cannot afford anything but the best in the care of frequently disabling disorders of the brain. Thank you for your consideration.

Sincerely,

Steven T. DeKosky, M.D.

Mark L. Scheuer, M.D.
Associate Professor of Neurology
Director, Epilepsy Center, Adult

Anto Bagic, M.D.
Assistant Professor of Neurology and Neurosurgery
Director, Magnetoencephalography Center

Submitter : Dr. Jeffrey Weber

Date: 09/14/2005

Organization : BryanLGH Medical Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

- A June 30, 2005, report on hospital outpatient department pharmacy handling costs prepared by the Medicare Payment Advisory Commission (MedPAC) noted that these expenses were "not insignificant" and that they "made up 26 percent to 28 percent of pharmacy departments' direct costs." Instead of accepting MedPAC's analysis, CMS proposes to pay only ?an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs."

- This reimbursement formula is inadequate to cover handling costs of drugs. Small hospitals, particularly, may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

- Support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

- CMS must collect hospital charge data for overhead costs for two years to determine if even the 8% rate is adequate and consider new reimbursement rates for these costs for payment in 2008.

Submitter : Ms. Eileen Jones

Organization : The Gift of Hearing Foundation

Category : Other Association

Date: 09/14/2005

Issue Areas/Comments

GENERAL

GENERAL

Please know the proposed cut in outpatient payment rates is at least a travesty. I speak specifically about the expenses for cochlear implants which already far exceed the existing reimbursement making it quite difficult for people to afford the differential. Cochlear implants are not like hearing aids that help people hear better -- they help deaf people hear!!!! This makes functional human beings -- puts people back into jobs and independent lives. Please consider INCREASING the reimbursement amounts for this very valuable and vital surgery. More cuts means fewer facilities will provide them and fewer people will get them -- the dominoe principle of cutting reimbursement gravely affects other areas of qualities of life and other government support systems. Please feel free to contact me for more information, and thank you for listening. Eileen Jones, Founder, The Gift of Hearing Foundation

Submitter : Elizabeth Rose

Organization : Vasomedical Inc.

Category : Device Industry

Date: 09/14/2005

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-395-Attach-1.DOC

Vasomedical Inc.
180 Linden Avenue · Westbury, NY 11590 · USA · Tel: 800-455-EECP 516-997-4600 Fax: 516-997-2299
EECP

September 13, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

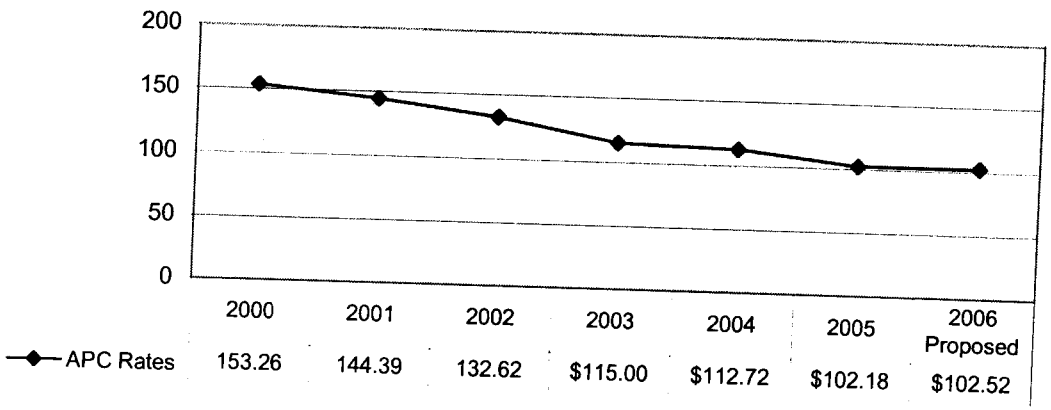
RE: **CMS – 1501 – P**
2006 Proposed Rule – Medicare Program:
Changes to the Hospital Outpatient Prospective Payment System
APC 0678/HCPCS G0166, External Counterpulsation

Dear Dr. McClellan:

Thank you for the opportunity to submit comments with regard to the 2006 Proposed Rule for the Medicare Hospital Outpatient Prospective Payment System, CMS – 1501- P. The 2006 Proposed Rule for HOPPS for APC 0678/HCPCS G0166, External Counterpulsation (ECP), indicates a proposed hospital outpatient rate of $102.52 in 2006, a slight increase of 0.33% compared to the 5.4% increase overall in Medicare OPPS rates for 2006 versus 2005.

Table 1
Medicare Hospital Outpatient Payments 2000-2006 for APC 0678 /HCPCS G0166, External Counterpulsation
Source: CMS Files 2000 – 2006 Proposed Rule for Hospital OPPS

2006 Proposed Hospital OPPS Fees
APC 0678 Medicare Rate



Our areas of concern stem from the declining trend in the APC 0678 Medicare Payment rate and include:

- Hospitals serve a large Medicare population whose access to ECP has been negatively impacted by a decline in OPPS rates for ECP therapy of 10% annually over the last 5 years, or 50.7% overall.
- The negative impact caused by the reduction in the Relative Weight to 1.73, reflecting a decrease of 3.65% compared to 2005 and a cumulative decrease since 2004 of 16%.
- The fact that this declining rate is not reflective of healthcare trends and hospital expenses incurred.

Background

Vasomedical Inc. is the manufacturer for EECP® external counterpulsation therapy. EECP® external counterpulsation therapy is a non-invasive; outpatient based treatment for patients with cardiovascular disease involving myocardial ischemia and is indicated for use in stable and unstable angina pectoris, congestive heart failure, acute myocardial infarction, and cardiogenic shock.

As of July 1, 1999 HCFA, now CMS, issued a national decision to provide coverage for external counterpulsation therapy to Medicare p atients diagnosed with disabling angina (class III or class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon are not readily amenable to surgical intervention, such as PTCA or cardiac bypass, due to any of the following medical circumstances:

1. Their condition is inoperable, or at high-risk of operative complications or post-operative failure
2. Their coronary anatomy is not readily amenable to such procedures
3. They have co-morbidities which create excessive risk

External counterpulsation requires an investment in capital equipment and disposable supplies for each treatment. The procedure requires a physician to provide direct supervision and a specially trained nurse to evaluate and monitor the patient prior to, during and following the one-hour treatment session. Patients spend approximately 90 – 120 minutes in the practice setting per one-hour treatment session as the staff conducts assessment, patient education and post treatment evaluations. Patients receive a total of 35 one-hour treatment sessions in the usual course of therapy, although the actual amount of staff and physician time is more typically in excess of 50 hours.

HCPCS code G0166, External Counterpulsation, has been in place since the 2000 Medicare Physician Fee Schedule. Since 2000, the APC code 0678 has been in place.

Clinical & Economic Benefits

Clinical and economic benefits of EECP® therapy in patients with angina or heart failure include:

- Improvement in symptoms,
- Improvement in functional status and the ability to engage in activities of daily living,
- Improvement in quality of life,
- For angina patients, an incremental cost of only $3,126 for each quality-adjusted life year (QALY) gained compared to conventional medical therapy, and
- Reduction in emergency room and hospital visits, as demonstrated in separate single-institution studies.

These benefits are being achieved in some of the most difficult-to-treat patients with cardiovascular disease and multiple co morbidities and in whom opportunities to reduce excessive utilization of health care resources abound.

Given the burden of healthcare costs associated with treating patients with angina and heart failure, these benefits can not be fully realized if reimbursement rates continue to pose a disincentive for hospitals to offer EECP® therapy.

Hospital Claims

Our review of claims data for 2004 indicates that there is a significant variability among hospital reimbursement and cost data, and it appears that there is a significant range of reimbursement rates among hospitals. This volatility in the Medicare reimbursement places an economic disincentive on the hospitals to acquire technology and treat appropriate Medicare populations for indications such as angina and heart failure.

While, we appreciate the efforts made by CMS to increase payment accuracy for outpatient therapies such as ECP therapy, we support the comments provided both by the Medical Device Manufacturers Association (letter dated August 4, 2005 to Shirl Ackerman-Ross) and AdvaMed (July 20,2005) that basing payment rates on historical claims data negatively impacts the median cost basis for the 2006 rates and does not accurately reflect the costs of devices. Both MDMA and AdvaMed have suggested that external data from independent organizations and companies be used to assist in the formulation of accurate payment rates. Vasomedical Inc. would be happy to assist in this effort.

We request reconsideration of the use of these data as a basis for setting the median cost and are willing to work with CMS as warranted to assure appropriate claims reporting as per CMS guidance. As a result, we are requesting CMS reconsider the reduction of the Relative Weight value, maintaining 2005 level of 1.79 which when considered with the 2006 conversion factor o f 59.34 w ill p rovide a APC rate of $106.22 or an increase of 4% for 2006, well within the overall increase of 5.4% proposed by CMS for the hospital outpatient payment system overall.

Medicare Hospital OPPS Payments 2000-2006 for APC 0678/G0166 ECP

Year	Median Cost	Relative Weight	Conversion Factor	APC Rate	% Chg.
2000				**$153.26**	
2001				**$144.39**	**(5.8)**
2002				**$132.62**	**(8.2)**
2003				**$115.00**	**(13.3)**
2004	120.84	2.07	54.56	**$112.72**	**(2)**
2005	105.00	1.79	57.10	**$102.18**	**(9.4)**
2006 Proposed Rule	104.25	1.73	59.34	**$102.52**	**0.33**
Vasomedical Public Comment		1.79	59.34	**$106.22**	**4**

If you have any questions or comments, please contact me at 516 997-4600 ext 154. Thank you again for the opportunity to provide these comments.

Sincerely,

Elizabeth Rose
Director, Market Development
Vasomedical Inc.

Submitter : John Settlemyer

Date: 09/14/2005

Organization : Carolinas HealthCare System

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please refer to the attached document for complete comments.

CMS-1501-P-396-Attach-1.PDF

September 14, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

RE: File Code CMS-1501-P
SUBMITTED ELECTRONICALLY

Thank you for the opportunity to provide comments on the 2006 OPPS proposed rule as follows:

New Procedure Codes (page 42712)

Please review and include all CPT Category III codes that will become effective on January 1, 2006 (codes 0089T – 0154T as published on the AMA website) in the final Addendum B and designate the codes to the most appropriate APC.

Please specifically review the following codes:

0115T – Medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, initial 15 minutes, with assessment, and intervention if provided; initial encounter

0116T – subsequent encounter

0117T – each additional 15 minutes (add-on code for either of the above)

According to Daniel Buffington, a pharmacist on the CPT editorial panel's Health Care Professionals Advisory Committee, these codes were created to "articulate pharmacy services in general, regardless of the payer type or practice setting" and the "CPT editorial panel themselves struggled making sure that what was produced in terms of coding was not to be confused as being limited to a Medicare Part D beneficiary".

Medicare beneficiaries frequently need medically necessary medication management / monitoring for optimal safe and therapeutic drug efficacy, and this occurs by pharmacists via "incident-to" provisions in both the OPPS and Physician office settings across the country. This is direct, face-to-face patient care that, in the long run reduces additional IP and OP expenditures. Sometimes this is limited to a very specific medication (neither multiple conditions nor multiple drugs involved) so it will not meet the definition of MTMS as defined in the Part D benefit.

Hospitals across the country have been providing medically necessary physician-ordered pharmacist management services in the OP setting, and providers typically include this type of service under their criteria for OP/Clinic Visit assignment.

These services do not need to be assigned to New Technology APCs, and CMS has even instructed providers to bill for this type of service as a low-level clinic visit. CMS previously posted an FAQ on its website (Answer ID 2101, which is no longer available) that states "when a face-to-face medication therapy management is provided by qualified hospital staff…a hospital may bill CPT 99211 if the

services are medically necessary and constitute a distinct, separately identifiable E/M service that is consistent with the hospital's criteria for a low-level clinic visit."

We recommend the following designation:

0115T	SI "V"	APC 601
0116T	SI "V"	APC 600
0117T	SI "N"	

Non-Pass Throughs (begins on 42723)

CMS proposes to discontinue A4644-A4646 for LOCM and begin using Q9945-Q9951, as well as begin paying separately for LOCM. The payment rates in Addendum B look a little strange, as the payment rate diminishes for higher concentrations of iodine. This seems counterintuitive. CMS points out that the claims data used represent many different variations of ML doses being billed at the various levels of iodine as reflected in A4644-A4646, so therefore you may have flawed assumptions in crossing that over to the 1ML Q-codes.

Additionally, why are the HOCM codes (Q9958-Q9964) not included in Addendum B and in this proposed methodology change? We would point out that in the Physician's Proposed Rule, CMS proposes to change the methodology for HOCM and remove it from the PE component; allowing for separate payment of HOCM. Physicians are already paid separately for the LOCM Q-codes.

If CMS moves forward with separate payment for LOCM, then it should also make separate payment for HOCM in the Hospital Outpatient setting.

DRUG ADMINISTRATION (begins on 42737)

CMS proposes to require the use of new CPT codes (which are currently being used on the physician's side as temporary HCPCS codes) for drug administration in 2006. The AMA has graciously agreed to post the Drug Administration information on its website so that providers may have the opportunity to review the codes and formulate comments to CMS during the OPPS comment period. CMS is proposing, as in 2005, for hospitals to bill all relevant CPT codes for services provided, and "payment for services within the same APC group would be collapsed by the OCE into a single per-visit APC payment" unless a modifier -59 is present to delineate a separate encounter.

Before proceeding with discussion of the codes, we would like to remind CMS that drug administration charges are generally assigned on a department-specific basis at the point of care. That is, the CPT codes are embedded in the chargemaster and the departmental personnel are responsible for charging based on the services provided to the patient while in their care. CMS should consider the following:

- Having separate codes for initial, subsequent and concurrent infusions may be virtually impossible to implement in hospitals, because patients often move from one to another care area, and drug administration charges are most often charged by the respective department in real-time.
- Without the benefit of a grace period, it is essential that CMS think about the implementation effects of a significant coding change/restructure for drug administration, as this is handled through chargemasters and not through the HIM coders. There is a significant amount of education and training that may be necessary for the point-of-care

persons who enter the charges across multiple locations and shifts.

- As a general rule, HIM coders do not assign coding or charges for drug administration.

We have reviewed the CPT codes for 2006 and find that virtually all of the information that was communicated to the physician side in 2005 (for use with G-codes) and some of the information communicated to hospitals (for instance an IV Push defined as an infusion of 15 minutes or less) have been incorporated into CPT language. We urge CMS to carefully review these preview CPT codes and all the previous transmittals that have been published in relation to OPPS billing for drug administration. The narrative contains multiple references to "physician supervision" and advanced practice training for administering staff. We would expect CMS to follow precedent and instruct providers to disregard this language. CMS in the past has instructed providers to "ignore" certain parts of CPT definition and/or narrative as it relates to the provision of hospital services, and we would expect the same treatment for Drug Administration.

Last year, we supported CMS' proposal to require providers to use CPT codes to report drug administration services. However, we along with other providers have struggled with the implementation and use of these codes in part due to lack of timely and correct guidance from CMS. The proposal to use the new CPT 2006 codes will exponentially increase the burden of correctly assigning charges.

The new codes were created in response to MMA mandate, and were implemented without any input from the hospital community. They were designed to pay physicians for each and every instance or combination of drug administration service(s). If implemented without exception, the new codes will be virtually impossible for hospitals to implement without changing current processes. It would require that medical records coders become involved in the assignment of CPT codes, because the staff (currently responsible for entering charges) that care for patients who move from department to department will not be able to determine what drug administration services provided in their respective department are "initial" or "sequential".

For instance, a patient may be scheduled for a chemotherapy visit. During the course of that visit, an emergency medical condition arises and the patient is taken to the ER. The patient is stabilized and goes to an observation bed. Drug administration may occur in each one of these care settings. In addition, if implemented without exception, the nomenclature could result in non-payment for services we are currently receiving payment for. If a patient has a one hour chemotherapy IV infusion and a medically necessary one hour hydration prior to the chemo, under proposed coding convention, the CPT services assigned would be as follows:

96413 – Chemo admin, IV infusion up to 1 hour (maps to APC 0117)
90761 – IV infusion, hydration ("Report 90761 to identify hydration as a secondary or subsequent service after a different initial service [..., 96413] is provided") – (maps to status "N"; currently paid under 90780 and APC 0120).

This will clearly create an underpayment problem that CMS has surely not intended to happen. We would like to provide the following proposal for your consideration as follows.

2005 CPT Code	2006 CPT Code (Preview)	2006 Description (Preview)	Recommendations
90780	90760	Intravenous infusion, hydration; initial, up to one hour.	SI "S", APC 0120. Ignore "initial" concept. Clearly define hydration.
90781	90761	Intravenous infusion, hydration; each additional hour, up to eight (8) hours.	SI "N". Clarify usage for hydration infusions that exceed 8 hours.
90780	90765	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to one hour.	SI "S", APC 0120. Ignore "initial" concept. Clearly define concepts of therapy, prophylaxis, diagnosis.
90781	90766	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour, up to eight (8) hours.	SI "N". Clarify usage for infusions that exceed 8 hours.
n/a	90767	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); additional sequential infusion, up to one hour.	SI "N". Define sequential.
n/a	90768	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); concurrent infusion.	SI" X, APC 0120. Define concurrent. Allow two payments for APC 0120 when this code is reported with 90760 or 90765.
90782 and 90788	90772	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); subcutaneous or intramuscular.	SI "X", APC 0353
90783	90773	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intra-arterial.	SI "X", APC 0359
90784	90774	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug.	SI "X", APC 0359. Ignore "initial" concept. Clarify definition of single substance/drug.

90784	90775	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug.	SI "X", APC 0359. Clarify definition of NEW substance/drug. Does this mean we cannot bill for multiple injections of the first drug?
90799	90779	Unlisted therapeutic, prophylactic or diagnostic intravenous or intra-arterial injection or infusion.	SI "X", APC 0353
96400	96401	Chemotherapy administration, subcutaneous or intramuscular; non-hormonal anti-neoplastic.	SI "S", APC 0116.
96400	96402	Chemotherapy administration, subcutaneous or intramuscular; hormonal anti-neoplastic.	SI "S", APC 0116.
96405	96405	Chemotherapy administration; intralesional, up to and including 7 lesions.	SI "S", APC 0116.
96406	96406	Chemotherapy administration; intralesional, more than 7 lesions.	SI "S", APC 0116.
96408	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug.	SI "S", APC 0116. Ignore "initial" concept. Clarify definition of single substance/drug.
96408	96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug.	CMS does not currently allow multiple payments for 96408 on the hospital side even though physician offices receive payment. Would this be "N"?
96410	96413	Chemotherapy administration; intravenous infusion technique; up to one hour, single or initial substance/drug.	SI "S", APC 0117. Ignore "initial" concept. Define concurrent. Clarify definition of single substance/drug.
96412	96415	Chemotherapy administration; intravenous infusion technique; each additional hour, 1 to 8 hours.	SI "N"
96414	96416	Chemotherapy administration; intravenous infusion technique; initiation of prolonged chemotherapy infusion (more than 8 hours), requiring use of a portable or implantable pump.	SI "S", APC 0117.

96412	96417	Chemotherapy administration; intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour.	SI "N". Define sequential.
96420	96420	Chemotherapy administration, intra-arterial; push technique	SI "S", APC 0116.
96422	96422	Chemotherapy administration, intra-arterial; infusion technique, up to one hour.	SI "S", APC 0117. Does not state "initial" but still ignore concept.
96423	96423	Chemotherapy administration, intra-arterial; infusion technique, each additional hour up to 8 hours.	SI "N"
96425	96425	Chemotherapy administration, intra-arterial; infusion technique, initiation of prolonged infusion (more than 8 hours), requiring the use of a portable or implantable pump.	SI "S", APC 0117.
96440	96440	Chemotherapy administration into pleural cavity, requiring and including thoracentesis	SI "S", APC 0116.
96445	96445	Chemotherapy administration into peritoneal cavity, requiring and including peritoneocentesis.	SI "S", APC 0116.
96450	96450	Chemotherapy administration, into CNS (eg, intrathecal), requiring and including spinal puncture.	SI "S", APC 0116.
96520	96521	Refilling and maintenance of portable pump.	SI "T", APC 0125
96530	96522	Refilling and maintenance of implantable pump or reservoir for drug delivery, systemic (eg, intravenous, intra-arterial)	SI "T", APC 0125
n/a	96523	Irrigation of implanted venous access device for drug delivery systems	SI "Q", payable when it is the only procedure performed.
96542	96542	Chemotherapy injection, subarachnoid or intraventricular via subcutaneous reservoir, single or multiple agents.	SI "S", APC 0116
96549	96549	Unlisted chemotherapy procedure.	SI "S", APC 0116

We would expect several things. First, that CMS clearly define all concepts of sequential, concurrent, diagnostic, prophylactic, and therapeutic as noted in the above table. Spell out what parts of CPT narrative may be ignored for hospitals. Second, CMS should continue to allow providers to apply the codes on a service-location basis (each department would charge for what happens in their department based on the applicable codes), as opposed to a visit or claim level basis. If CMS implements the new codes on a visit basis, the coding and charging of drug administration will have to revert to the HIM department, and will slow down bill processing as well as increase the burden of resources on providers. Even if reported on a departmental basis, we understand that CMS will only pay one APC payment for each infusion category per visit. Injections would still continue to receive multiple APC payments as they always have.

We would expect implementation guidance from CMS, if not included in the Final Rule, no later than November 30th, 2005, so that we may properly train our staffs in the use of the codes and be prepared to implement them on January 1st, 2006. This guidance should be free from contradictions and errors so that CMS does not have to release additional guidance or corrections many months after the codes are in place.

In regard to proposed changes for Vaccine Administration, we would like to thank CMS for recognizing the need to assign payment as stated in Table 28. We heartily support these changes. We would like to clarify what we believe to be a typo in the middle column of page 42739. Hospitals would code for hepatitis B vaccine administration using codes 90741 and 90742 (not 96471 and 96472 as listed in the proposed rule).

Payment Reduction of Diagnostic Imaging Services (begins on 42748)

CMS has proposed to apply a 50% discount when two or more diagnostic imaging procedures from the same family of codes are provided during one session because CMS assumes the provider gains economies to scale. Some economies to scale are generated when similar radiology procedures are performed during the same session, but we disagree with CMS' proposal to reduce the payment rate of the second and subsequent APCs by 50%.

Such a reduction ignores the fact that some of the economies to scale are already reflected in the cost-to-charge ratio used by CMS to arrive at the median cost data. Furthermore, CMS does not currently pay hospitals for procedures that take longer as a result of problems with the patient's clinical condition. If CMS implements a reduction in payments, then conversely a modifier (such as modifier –22) should also be established to indicate increased costs, when incurred. We advocate that the additional payment be made at the same percentage as the reduction in payment being considered. CMS should instruct hospitals to apply the increased cost modifier to any affected radiology procedure; and provide specific guidelines as to what events constitute increased cost, as well as documentation needed to support the modifier.

We are not clear on what CMS means by separate "session". If CMS proceeds with this proposal, the term "session" must be explicitly defined so that providers know when they can and should use modifier -59 to signify that multiple diagnostic radiology procedures were performed on the same date of service, but NOT during the same session. CMS will need to define "session" in a way that distinguishes it from other terms, such as "encounter" or "visit", so that hospitals will use modifier -59 appropriately in order to be paid 100% for both or all of the subsequent procedures provided (if done during different sessions).

Furthermore, CMS OPPS staff should work in tandem with the Physician's side as this recommendation has also been promulgated in the MPFS proposal for 2006. If CMS encounters

valid arguments on the physician's side and decides not to implement this in the MPFS, then it should also unilaterally not implement it on the hospital side either.

We urge CMS to delay implementation of this proposal until it has fully studied and analyzed both provider claims and cost report data to determine if, in fact, a further reduction in payment is warranted or if economies to scale are already being captured through the departmental cost-to-charge ratio. Also, CMS could consider working with the AMA to simply create new CPT codes that describe commonly combined procedures so that data can be more systematically collected and payment rates naturally set from provider charges for these combined procedures as reported through the claims data. This would ensure that the ordering physician intended for both exams to be performed and a single radiologist report would be produced that addresses the combined exams.

Thank you for your consideration.

Sincerely,

John Settlemyer
Director, Financial Services
Carolinas HealthCare System
PO Box 32861
Charlotte, NC 28232-2861

Submitter : Mr. Jerel Bullock

Date: 09/14/2005

Organization : University of Utah South Jordan Clinic

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am writing this letter in opposition to the proposed payment rates for 2006. The proposed rates will not cover pharmacy handling costs.

- A June 30, 2005, report on hospital outpatient department pharmacy handling costs prepared by the Medicare Payment Advisory Commission (MedPAC) noted that these expenses were "not insignificant" and that they "made up 26 percent to 28 percent of pharmacy departments' direct costs."

It is unclear to me why CMS proposes to pay only an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs instead of accepting MedPAC's analysis.

This reimbursement formula is clearly inadequate. A letter from ASHP states "Small hospitals, particularly, may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety, and level of their services". Ultimately, this proposal will be far more costly to the healthcare system than would be the cost of a fair and equitable reimbursement rate.

I support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost. CMS must collect hospital charge data for overhead costs for two years to determine if even the 8% rate is adequate and consider new reimbursement rates for these costs for payment in 2008.

Thank You,

Jerel Bullock, RPh
University of Utah South Jordan Clinic

Submitter : Dr. Michael Repka

Organization : American Academy of Ophthalmology

Category : Health Care Professional or Association

Date: 09/14/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-398-Attach-1.PDF

AMERICAN ACADEMY OF OPHTHALMOLOGY
The Eye M.D. Association

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Federal Affairs Department

September 14, 2005

via Electronic Mail
Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-150-P (Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates)

Dear Dr. McClellan:

On behalf of the American Academy of Ophthalmology (Academy) I am writing to comment on the Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. The Academy is the world's largest organization of eye physicians and surgeons, with more than 27,500 members. Over 16,000 of our members are in active practice in the United States. We appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule.

The Academy was pleased to note that several of the provisions in the proposed rule address ophthalmology issues and promote access to technology that advances eye health. However, we are concerned that some of the proposed changes may adversely impact the availability and performance of ophthalmology services in the hospital outpatient department. Among our concerns is movement of the new patient eye exam and eye exam treatment codes to lower paying APC groupings. The Academy urges CMS to consider and subsequently adopt the recommendations included in this comment letter.

2 Times Rule

The Academy is pleased with the recommendation to exempt the Level I posterior segment eye procedures from the 2 Times Rule and to keep these procedures in APC group 0235. The Academy is also pleased with the decision to move several other ophthalmology procedures into higher paying APC groups among them: 65265, 65285, 66220, 67025, 67027, 67036, 67038, 67039, and 67121. These changes will ensure that reimbursement for these procedures will remain at a fair level when they are performed in the outpatient department.

Despite these positive changes, the Academy questions the decision of CMS to move ophthalmology codes 92004 and 92014 to the lower paying APC group 0601. 92004 and 92014 are comprehensive eye exam codes. One represents treatment for a new patient while the other represents treatment for an established patient. The procedure for performing these codes in the hospital outpatient setting has not drastically changed in the past year yet CMS is proposing that the payment associated with these two procedures be reduced from APC 602 high level clinic visits to APC 601 mid-level clinic visits. Changing the APC group for these codes would result in a reduction in payment of $25.10 for each procedure. We urge CMS to reconsider this decision and to allow these codes to remain in APC group 0602.

Over the past year the Academy has been made aware of instances where some hospital outpatient departments no longer allow certain procedures such as cataract removal - 66984- to be performed in the outpatient department because of low reimbursement. This is a trend that we anticipate will grow if the APC rates associated with these procedures are cut. We therefore strongly urge CMS to keep 92004 and 92014 in APC group 0602.

New Technology APCs

The Academy supports CMS's proposal to introduce additional payment increments for new technology APCs. The introduction of payment groups in $10 increments should ease the introduction of new and innovative technology into the outpatient setting to the benefit of both physicians and patients.

Transitional Pass-Through Payments for Devices

The Academy notes that the transitional pass-through period will expire for two ophthalmology devices, retinal tamponade device (silicone oil) and integrated keratoprosthesis, effective December 31, 2005. The Academy asks that these two devices and their costs be incorporated into the appropriate APC group to ensure proper payment for services utilizing these valuable tools in the future.

Retinal tamponade device, silicone oil (C1814) is used by surgeons treating complex retinal detachments. As such the Academy wants to ensure that this code is packaged with the HCPCS codes with which the device is typically billed. We would recommend that C1814 be packaged with the following HCPCS code(s): 67036-67040, 67108, and 67112. All of these codes are either currently or proposed to be reimbursed under APC group 0672.

Similarly, integrated keratoprosthesis (C1818) is used by surgeons treating central cornea disease. We would recommend that C1818 be billed with the HCPCS code 65770 at the expiration of its pass-through status. 65770 is reimbursed under APC group 0244.

Pass-Through Device Categories

In response to comments, CMS is proposing to include another category for devices to qualify for pass-through status. The Academy supports implementation of this "new device" category which will allow devices that meet the existing criteria for pass-through status but do not fit into an existing category descriptor to qualify.

CMS is proposing that devices included in the "new device" category meet two criteria: the applicant must show that the device does not fit into an existing device category and the applicant must demonstrate that utilization of the device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments.

While the Academy understands the need to develop criteria for establishing new device categories, it is concerned with the standards outlined in the proposed rule. The Academy's primary concern regards enforcement and evaluation of the second criteria. We are concerned that CMS has not developed standards for what constitutes proof of "substantial clinical improvement". This term has many meanings in medical research. There are also issues as to whether expert opinion, clinical trials, or other protocol data will be required as proof of meeting this standard. The Academy encourages CMS to further clarify the intentions of this standard before including it in the final rule

Non Pass-Throughs

Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

The Academy supports CMS's continued use of packaged and separate payment systems, depending on the median per day cost of drugs, in establishing payment for drugs, biologicals, and radiopharmaceuticals that do not have pass-through status. The per day cost for verteporfin, a drug used by ophthalmologists, exceeds $50 and is typically paid separately. The method proposed by CMS for paying for this drug and others like it allows hospital outpatient departments to procure these drugs at a reasonable price while also ensuring that the Medicare program is only billed for the actual amount of drug used. This system also allows hospital outpatient departments to have an efficient option, packaging, for collecting payments for less costly drugs.

Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status That Are Not Packaged: 3 (a) (4) CY 2006 Proposed Payment Policy for Radiopharmaceutical Agents

The Academy supports CMS's recommendation to pay separately for radiopharmaceuticals based on the hospital's charge for each agent adjusted to cost in 2006. We are concerned that rapid fluctuation in payment rates for these drugs can result in diminished beneficiary access. By 2007 there should be adequate ASP data to verify the costs of these drugs and allow stability in the pricing system.

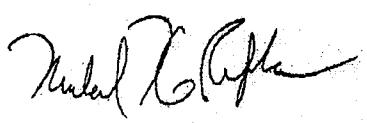
3(b) Proposed CY 2006 Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals With HCPCS Codes, But Without OPPS Hospital Claims Data

The proposed rule recommends pricing drugs that have a HCPS code but do not have pass-through status at the rate at which they would have been paid in the physician's office setting, in accordance with ASP methodology. These codes are identified with a HCPCS indicator of "K". The Academy supports adoption of this payment method which encompasses payment for verteporfin (Visudyne) J3396 and pegaptanib C9128. The price of verteporfin has undergone tremendous fluctuations over the past several years. Pegaptanib has not been on the market for a full year, but is potentially subject to these same fluctuations. Pricing these drugs in the hospital outpatient setting at a cost comparable to that for physician offices will encourage hospitals to procure the drugs and to allow physicians who perform procedures utilizing them to do so in the outpatient department.

Conclusion

It is our hope that CMS will give serious consideration to the Academy's recommendations regarding the proposed hospital outpatient prospective payment system rule. We encourage CMS to adopt our recommendation to leave 92004 and 92014 in their current APC groups and to package the costs for retinal tamponade device, silicone oil and integrated keratoprosthesis with the APC groups identified in these comments. Again, the Academy would like to thank you for providing us with the opportunity to comment and looks forward to CMS's response.

Sincerely,



Michael X. Repka, M.D.
Secretary of Federal Affairs

Submitter : David Matteodo

Date: 09/14/2005

Organization : Ma. Association of Behavioral Health Systems

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1501-P-399-Attach-1.DOC

Massachusetts Association of Behavioral Health Systems, Inc.

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Nasir Khan, M.D.
President

David Matteodo
Executive Director

VIA ELECTRONIC MAIL and Regular Mail

September 14, 2005

Mark McClellan, M.D. PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop: C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

RE: CMS-1501-P: Proposed Changes to Hospital Outpatient PPS

Dear Dr. McClellan,

On behalf of the Massachusetts Association of Behavioral Health Systems (MABHS), a statewide organization of 44 hospitals, I appreciate the opportunity to offer these comments regarding proposed Partial Hospital rates. We are extremely concerned that the proposed 15% payment reduction to Partial Hospitals may result in significant problems for our Partial Hospital programs and threatens their ongoing viability.

In Massachusetts, we have seen the situation where several years ago, there was a strong push from government and insurers to provide Partial Hospital services as a less expensive alternative to inpatient care. It also was perceived as beneficial to patients because it could provide them with extensive services, yet allow patients to remain in the community and avoid hospitalization. Many of our hospitals stepped forward and enthusiastically began providing Partial Hospital services. Patients seemed to like it, and clearly the programs had provided significant benefits.

Unfortunately, it seems that much of the initial interest in the service has waned significantly among government and insurers. We have seen programs close in Massachusetts because they could not maintain their fiscal viability. These closures are particularly unfortunate in certain parts of the State, where geographically it is not feasible for patients to travel far distances to another program. Once programs close, most if not all will probably not reopen. We have seen this occurrence with the Detoxification Programs in Massachusetts, many of which closed due to State Budget cuts, only to not reopen when conditions improved.

We fear the proposed 15% payment reduction for beginning in January, 2006 will place an additional enormous strain on our programs. We understand that a major reason why the rate cut is being proposed by CMS is because of unreliable data from the Community Mental Health Centers and that CMS would like the CMHC's to develop a more reliable reporting methodology. That certainly seems reasonable

given some of the variances CMS has seen over the past few years. However, we believe it would be far better to maintain the current rate structure until a payment methodology which is derived from more reliable data is developed This would help providers understand better why they are being reimbursed a particular rate while also allowing CMS to have a methodology with which it is more comfortable.

We are aware that the National Association of Psychiatric Health Systems has submitted more detailed comments on this matter. We strongly support those comments. Many of our programs are also represented by NAPHS and we urge CMS to give serious consideration to their comments.

Please do not reduce the rates for Partial Hospital programs for 2006; but rather delay any consideration of a rate cut until a more reliable reporting methodology is devised. Surely CMS does not want to see further closures or erosion of this very important service.

Thank you for the opportunity to offer these comments. Should you have any questions, please do not hesitate to contact me.

Sincerely,

David Matteodo, Executive Director
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